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| FOR: SURGICAL INSTRUMENT AND METHOD | : | |

LETTER

Mail Stop DD
Commissioner for Patents
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SIR:

Submitted herewith are modifications to the European application, which were filed in the European Patent Office in accordance with the suggestions provided at the Oral Proceedings before the EPO Examining Division on December 7, 2005, for the Examiner's consideration.

Respectfully submitted,

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01 98 5084.1
American Medical Systems, Inc.
Our Ref.: G2515 EP

December 13, 2005
VI/ASP

Reference is made to the Oral Proceedings before the Examining Division on December 7, 2005:

1. Enclosed please find an amended version of amended page 13 of the description submitted during the oral proceedings. At the end of this page, publication number EP-A-1 353 598 has been added. We furthermore enclose herewith a clean copy of the description, the claims and the drawings submitted during the oral proceedings.

   We also enclose herewith a new set of claims with claims 1-9. New claims 1-9 are identical to claims 1-9 submitted during the hearing. However, additional reference numerals have been added.

2. It is requested that now the Communication under Rule 51(4) EPC be issued.

Rainer Viktor
European Patent Attorney

Encl.
Amended page 13
Clean copy of the description, the claims and the drawings

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**New Claims:**

1. A surgical needle (60, 60B) and handle (64, 64B, 64G, 64H, 64I, 64J, 64K) combination for implanting a sling (42) within the body of a patient, the needle and handle combination comprising:

an elongate arcuate needle (60, 60B) that is sized and shaped to withstand forces encountered during a sling implantation procedure, the needle (60, 60B) having first and second ends (58, 62, 62B), at least one of the needle ends adapted to be selectively associated with a sling (42), and at least one of the needle ends having a handle engagement surface comprising a keying feature (170);

a handle (64, 64B, 64H, 64I, 64J, 64K), the handle (64, 64B, 64H, 64I, 64J, 64K) including a needle end engagement surface comprising a keying feature (178, 200, 222, 222B, 222K) that is complementary in shape to the keying feature (170) of said handle engagement surface; and

handle repositioning means for moving at least one of the needle end engagement surface and the handle engagement surface between a) one of a number of engaged positions with the keying feature (178, 200, 222, 222B, 222K) of the needle end engagement surface contacting the keying feature (170) of the handle engagement surface to orient the handle to the arc of the arcuate needle (60, 60B) in each such engaged position, wherein each engaged position corresponds to a different orientation of the handle relative o the needle, and to resist relative axial and rotational movement between the needle and handle, and b) a release position, spaced from the engaged positions, which affords relative movement of the handle and the needle, characterized in that the complementary keying features allow a user to rotatably index the handle between predetermined positions located in ninety-degree increments around the needle axis.

2. A combination according to claim 1, further comprising at least one dilator (54) associated with a sling end as a sling assembly, wherein the first end of the needle has attachment means for associating with either a releasably attachable handle or a dilator associated with the sling, and the second end of the needle has attachment means for associating with either a releasably attachable handle or a dilator of the sling assembly.

3. A combination according to claim 1 wherein the handle repositioning means affords rotational movement and repositioning of the handle relative to the needle.

4. A combination according to claim 1 wherein the handle repositioning means affords axial movement and repositioning of the handle relative to the needle.

5. A combination according to claim 1 further including a second handle.

6. A combination according to claim 1 wherein the handle has first and second opposite ends and the needle emerges from the handle at a second end of the handle, and

the handle repositioning means comprises a button (198, 202) situated near the second end of the handle (64, 64B, 64G, 64H) for actuating the needle end engagement surface.

7. A combination according to claim 1 wherein the handle has first and second opposite ends and the needle emerges from the handle at a second end of the handle, and

the handle repositioning means comprises a button (198, 202) situated near the first end of the handle (64, 64B, 64G, 64H) for actuating the needle end engagement surface.

8. A combination according to claim 1 wherein the handle and the handle repositioning means comprises a unitary structure.

9. A combination according to claim 1 wherein the arcuate needle (60, 60B) comprises a needle shaft bent into a needle arc thereby defining a needle arc plane;

the handle has a handle plane and a handle axis; and

the handle repositioning means enables engagement of the needle end engagement surface and the handle engagement surface in the number of engaged positions each disposing the arc plane in different axial angular relation to the handle axis and handle plane to change the orientation of the needle to the handle.

**Claims:**

1. A surgical needle (60) and handle (64) combination for implanting a sling (42) within the body of a patient, the needle and handle combination comprising:

an elongate arcuate needle (60) that is sized and shaped to withstand forces encountered during a sling implantation procedure, the needle (60) having first and second ends (58, 62), at least one of the needle ends adapted to be selectively associated with a sling (42), and at least one of the needle ends having a handle engagement surface comprising a keying feature (170);

a handle (64), the handle (64) including a needle end engagement surface comprising a keying feature (200) that is complementary in shape to the keying feature (170) of said handle engagement surface; and

handle repositioning means for moving at least one of the needle end engagement surface and the handle engagement surface between a) one of a number of engaged positions with the keying feature (200) of the needle end engagement surface contacting the keying feature (170) of the handle engagement surface to orient the handle to the arc of the arcuate needle (60) in each such engaged position, wherein each engaged position corresponds to a different orientation of the handle relative o the needle, and to resist relative axial and rotational movement between the needle (60) and handle (64), and b) a release position, spaced from the engaged positions, which affords relative movement of the handle (64) and the needle (60), characterized in that the complementary keying features allow a user to rotatably index the handle between predetermined positions located in ninety-degree increments around the needle axis.

2. A combination according to claim 1, further comprising at least one dilator (54) associated with a sling end as a sling assembly, wherein the first end of the needle has attachment means for associating with either a releasably attachable handle or a dilator associated with the sling, and the second end of the needle has attachment means for associating with either a releasably attachable handle or a dilator of the sling assembly.

3. A combination according to claim 1 wherein the handle repositioning means affords rotational movement and repositioning of the handle relative to the needle.

4. A combination according to claim 1 wherein the handle repositioning means affords axial movement and repositioning of the handle relative to the needle.

5. A combination according to claim 1 further including a second handle.

6. A combination according to claim 1 wherein the handle has first and second opposite ends and the needle emerges from the handle at a second end of the handle, and

the handle repositioning means comprises a button (198) situated near the second end of the handle (64) for actuating the needle end engagement surface.

7. A combination according to claim 1 wherein the handle has first and second opposite ends and the needle emerges from the handle at a second end of the handle, and

the handle repositioning means comprises a button (198) situated near the first end of the handle (64) for actuating the needle end engagement surface.

8. A combination according to claim 1 wherein the handle and the handle repositioning means comprises a unitary structure.

9. A combination according to claim 1 wherein the arcuate needle comprises a needle shaft bent into a needle arc thereby defining a needle arc plane;

the handle has a handle plane and a handle axis; and

the handle repositioning means enables engagement of the needle end engagement surface and the handle engagement surface in the number of engaged positions each disposing the arc plane in different axial angular relation to the handle axis and handle plane to change the orientation of the needle to the handle.

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American Medical Systems, Inc
Our Ref.: G 2515 EP



# SURGICAL INSTRUMENT

**[0100]** Millions of men and women of all ages suffer from urinary incontinence. The social implications for an incontinent patient include loss of self-esteem, embarrassment, restriction of social and sexual activities, isolation, depression and, in some instances, dependence on caregivers. Incontinence is the most common reason for institutionalization of the elderly.

**[0101]** The urinary system consists of the kidneys, ureters, bladder and urethra. The bladder is a hollow, muscular, balloon-shaped sac that serves as a storage container for urine. The bladder is located behind the pubic bone and is protected by the pelvis. Ligaments hold the bladder in place and connect it to the pelvis and other tissue. Figure 1 schematically illustrates female anatomy. The urethra 16 is the tube that passes urine from the bladder 14 out of the body. The narrow, internal opening of the urethra 16 within the bladder 14 is the bladder neck 18. In this region, the bladder's bundled muscular fibers transition into a sphincteric striated muscle called the internal sphincter. Figure 2 schematically illustrates male anatomy. The urethra 16 extends from the bladder neck 18 to the end of the penis 22. The male urethra 16 is composed of three portions: the prostatic, bulbar and pendulus portions. The prostatic portion is the widest part of the tube, which passes through the prostate gland 24.

**[0102]** Incontinence may occur when the muscles of the urinary system malfunction or are weakened. Other factors, such as trauma to the urethral area, neurological injury, hormonal imbalance or medication side-effects, may also cause or contribute to incontinence. There are five basic types of incontinence: stress incontinence, urge incontinence, mixed incontinence, overflow incontinence and functional incontinence. Stress urinary incontinence (SUI) is the involuntary loss of urine that occurs due to sudden increases in intra-abdominal pressure resulting from activities such as coughing, sneezing, lifting, straining, exercise and, in severe cases, even simply changing body position. Urge incontinence, also termed "hyperactive bladder" "frequency/urgency syndrome" or "irritable bladder," occurs when an individual experiences the immediate need to urinate and loses bladder control before reaching the toilet. Mixed incontinence is the most common form of urinary incontinence. Inappropriate bladder contractions and weakened sphincter muscles usually cause this type of incontinence. Mixed incontinence is a combination of the symptoms for both stress and urge incontinence. Overflow incontinence is a constant dripping or

leakage of urine caused by an overfilled bladder. Functional incontinence results when a person has difficulty moving from one place to another. It is generally caused by factors outside the lower urinary tract, such as deficits in physical function and/or cognitive function.

**[0103]** A variety of treatment options are currently available to treat incontinence. Some of these treatment options include external devices, behavioral therapy (such as biofeedback, electrical stimulation, or Kegal exercises), injectable materials, prosthetic devices and/or surgery. Depending on age, medical condition, and personal preference, surgical procedures can be used to completely restore continence. One type of procedure, found to be an especially successful treatment option for SUI in both men and women, is a sling procedure.

**[0104]** A sling procedure is a surgical method involving the placement of a sling to stabilize or support the bladder neck or urethra. There are a variety of different sling procedures. Slings used for pubovaginal procedures differ in the type of material and anchoring methods. In some cases, the sling is placed under the bladder neck and secured via suspension sutures to a point of attachment (e.g. bone) through an abdominal and/or vaginal incision. Examples of sling procedures are disclosed in U.S. Pat. Nos. 5,112,344; 5,611,515; 5,842,478; 5,860,425; 5,899,909; 6,039,686, 6,042,534 and 6,110,101.

**[0105]** The present invention is specified by the claims. The present invention comprises a controllable surgical instrument suitable for implanting a surgical material such as a sling for treating incontinence. The invention includes a surgical needle and handle combination for implanting a sling. The present invention comprises an elongate arcuate needle that is sized and shaped to withstand forces encountered during a sling implantation procedure. The needle has first and second ends; means for associating the needle with a sling, and at least one of the ends having a handle engagement surface. The invention includes a handle having means for receiving at least one end of the needle. The handle includes a needle end engagement surface, and handle repositioning means for moving at least one of the needle end engagement surface and the handle engagement surface between a) an engaged position with the needle end engagement surface contacting the handle engagement surface to resist relative movement between the needle and handle, and b) a release position, spaced from the engaged position, which affords relative movement between the handle and the needle. The handle repositioning means may comprise many different structures such a buttons, cams and sliders. The structure (e.g. button) may be located at a proximal or distal end of the handle, or in a mid portion of the handle.

**[0106]** Preferably the first end of the needle has attachment means for associating with either a releasably attachable handle or a dilator associated with the sling, and the second end has attachment means for associating with either a releasably attachable handle or a dilator of the sling assembly.

**[0107]** In a preferred embodiment, the handle repositioning means affords rotational movement and repositioning of the handle relative to the needle. More preferably, the handle repositioning means affords axial movement and repositioning of the handle relative to the needle.

**[0108]** In another preferred embodiment, the invention includes a second handle, separate from the first handle and situated along the needle. Optionally, the handle repositioning means of the second handle includes means for moving the second handle axially toward the first handle and for resisting movement of the second handle axially away from the first handle. In this embodiment, the first handle includes means for moving and repositioning the first handle relative to the needle.

**[0109]** The article of the present invention may optionally include gripping means for enhancing manual grasping of the handle. Other optional features are contemplated. For example, a portion of the needle may extend within the handle along substantially the entire length of the handle to enhance attachment of the handle to the needle.

**[0110]** Other features and advantages of the present invention will be seen as the following description of particular embodiments progresses in conjunction with the drawings, in which:

**[0111]** Figure 1 is a schematic view of the female urinary system;

**[0112]** Figure 2 is a schematic view of the male urinary system;

**[0113]** Figure 3 is a perspective view of one embodiment of the sling delivery system of the present invention, showing the sling delivery system disassembled;

**[0114]** Figure 4A is a perspective view of a dilator according to an aspect of the present invention;

**[0115]** Figure 4B is a top view of the dilator of Figure 4A;

**[0116]** Figure 4C is a side view of the dilator of Figure 4A;

**[0117]** Figure 4D is a sectional view of the dilator of Figure 4A;

**[0118]** Figure 4E is a side view showing a dilator assembled to either a sheath or sling according to aspects of the present invention;

**[0119]** Figure 5 is a side view of an embodiment of needle, handle and slidable handle according to an aspect of the present invention;

**[0120]** Figure 6A is a perspective view of another embodiment of the dilator of the present invention and portions of a sling assembly or sling in a disassembled condition;

**[0121]** Figure 6B is a perspective view showing the dilator of Figure 6A and an insertion needle in a disassembled condition;

**[0122]** Figure 7 is a side view of another embodiment of the dilator of the present invention and portions of a sling or sling assembly, showing the dilator in an unassembled condition;

**[0123]** Figure 8A is a side view of a needle of the present invention;

**[0124]** Figure 8B is a side view of a portion of an embodiment of needle according to the present invention;

**[0125]** Figure 8C is a sectional view of a needle according to the present invention; taken approximately along the lines of 8C-8C in Figure 8B;

**[0126]** Figure 8D is a perspective view of an end portion of a needle according to an aspect of the present invention;

**[0127]** Figure 8E is an end view of a needle in an unseated position;

**[0128]** Figure 8F is an end view of a needle in a seated position;

**[0129]** Figures 9A-9E illustrate one embodiment of the handle of the present invention, wherein:

**[0130]** Figure 9A is a perspective view of the handle;

**[0131]** Figure 9B is a sectional view of the handle, showing elements in a disassembled condition;

**[0132]** Figure 9C is a sectional view of the handle of Figure 9A;

**[0133]** Figure 9D is a sectional view of the handle of Figure 9A showing elements in a locked position;

**[0134]** Figure 9E is a perspective view of the handle of Figure 9A showing elements in an unlocked position;

**[0135]** Figure 10A is a perspective view of another embodiment of the handle of the present invention, showing two handles and portions of mating needles,

**[0136]** Figure 10B is a perspective view of another embodiment of handle according to the present invention;

**[0137]** Figure 10C is a perspective view of another embodiment of handle according to the present invention;

**[0138]** Figure 11A is a perspective view of another handle according to the present invention;

**[0139]** Figure 11B is a sectional view of the handle of Figure 11A;

**[0140]** Figure 11C is an end view of the handle of Figure 11A;

**[0141]** Figure 12A is a side view of another embodiment of the handle of the present invention;

**[0142]** Figure 12B is another side view of another embodiment of handle according to the present invention;

**[0143]** Figure 13A is a side schematic illustration of one embodiment of a slidable handle and locking mechanism of the present invention;

**[0144]** Figure 13B is a schematic illustration of the slidable handle of Figure 13A;

**[0145]** Figure 14A is a schematic perspective view of another embodiment of slidable handle and locking mechanism of the present invention;

**[0146]** Figure 14B is a schematic view of portions of the slidable handle and locking mechanism of Figure 14A;

**[0147]** Figure 14C is a perspective view of a portion of the handle of Figure 14A;

**[0148]** Figure 15A is a perspective view of another embodiment of a slidable handle and locking mechanism of the present invention;

**[0149]** Figure 15B is a schematic perspective view of portions of the handle introduced in Figure 15A;

**[0150]** Figure 15C is a sectional view of elements of another handle according to the present invention;

**[0151]** Figure 15D is a sectional view of elements of another handle according to the present invention;

**[0152]** Figure 15E is a sectional view of elements of another handle according to the present invention;

**[0153]** Figure 16 is a schematic perspective view of elements of another handle according to the present invention;

**[0154]** Figure 17 is a sectional view of another embodiment of a slidable handle and locking mechanism of the present invention;

**[0155]** Figure 18 is a perspective view of another embodiment of a locking mechanism of a slidable handle of the present invention;

**[0156]** Figure 19 is a perspective view of elements of another embodiment of locking mechanism of a slidable handle of the present invention;

**[0157]** Figures 20A through 20D are perspective views sequentially showing the insertion of a needle suprapubically according to one aspect of the present invention, wherein:

**[0158]** Figure 20A shows the needle just passing an abdominal incision;

**[0159]** Figure 20B illustrates the needle as the surgeon seeks to identify the tactile feel of the resistance provided in part by the posterior portion of the pubic bone;

**[0160]** Figure 20C shows the needle as it passes along the posterior surface of the pubic bone which may be used as an anatomical guide for a surgeon as the needle approaches a vaginal incision;

**[0161]** Figure 20D illustrates the needle as it passes out of a vaginal incision;

**[0162]** Figure 21A is a schematic end view generally illustrating regions to avoid and preferred regions for needle passage in a patient;

**[0163]** Figure 21B is a schematic end view showing two needles placed in a patient and ready to receive a sling assembly;

**[0164]** Figure 21C is a perspective view of a sling system attached to two needles;

**[0165]** Figure 22 a schematic perspective view of an example of the method of use of the sling delivery system with respect to the male anatomy;

**[0166]** Figure 23 is a perspective view of another example of surgical procedure showing a needle being initially inserted into the body transvaginally as opposed to suprapubically;

**[0167]** Figure 24 is an end view of two surgical needles after being inserted in the body transvaginally as shown in Figure 23, showing handles of the needles on one end of the needles with dashed lines and using an arrow and solid lines to show that the handles are removed and reattached to the needles on the other ends of the needles,

**[0168]** Figure 25 is a perspective view of the needles of Figure 24 after a sling assembly has been attached;

**[0169]** Figure 26 is a top view of an alternative sling.

**[0170]** The following description is meant to be illustrative only and not limiting. Other embodiments of this invention will be apparent to those of ordinary skill in the art in view of this description.

**[0171]** Referring to Figure 3, an embodiment of assembly 40 includes a sling assembly 46 that includes a sling 42 for treating incontinence. The present invention is particularly suitable for treating stress urinary incontinence (SUI) diagnosed with urethral hypermobility or intrinsic sphincter deficiency in both men and women. Although the invention as disclosed herein generally refers to SUI, treatment of other urological disorders, such as urge incontinence, mixed incontinence, overflow incontinence, functional incontinence, prolapse (e.g. vaginal), enteroceles (e.g. of the uterus), rectoceles and other non-urological disorders, are also included within the scope of the present invention. It is contemplated that the present invention may also be utilized in

**[0172]** The sling assembly 46 preferably includes an implantable member (e.g. a hammock, sling or strip) 42 within a protective sheath 44. The sheath 44 is used during insertion of the strip 42. After the sling 42 is implanted, the sheath 44 is removed and discarded.

**[0173]** Each of the two ends 48, 50 of the elongate sling assembly 46 attaches to a first end 52 of a dilator 54 or needle-sling connector. The dilator 54 dilates a needle track for ease of sling introduction and positioning within the patient. A second end 56 of each dilator 54 is sized and shaped to quickly and securely connect to a first end 58 of a slim, arc-shaped needle 60. An adjustable handle 64 is preferably removably and repositionably attached to a second end 62 of the needle 60. Each end 58, 62 of the needle 60 is preferably keyed to allow for convenient, secure attachment of the needle 60 relative to the handle 64 and dilator 54. In a preferred embodiment, the key feature prevents rotation of the dilator 54 relative to the needle 60. Alternatively, the handle 64 may be rigidly affixed to the needle 60.

**[0174]** Details about the sling, the sheath, the tension adjustment member 66 can be found in EP-A-1 353 598.

**[0175]** The ends of the sheath are preferably connected to a dilator. Alternatively, the sheath may be connected to the sling, and the sling can be associated with the dilator. The number of dilators will depend on factors such as the shape of the sling. For example, the sling 42P shown in Figure 26 includes four dilators 54P.

**[0176]** At least two dilators are preferred. The sling 42 shown in Figure 3 includes two dilators. The first end 48 and second end 50 of the sheath 44 are preferably configured for attachment to a dilator 54.

**[0177]** The dilator 54 is a component that atraumatically creates and/or expands the passageway through the tissues for sling assembly delivery. The dilator 54 includes a means for associating with a needle 60. The dilator 60 is preferably short relative to a needle 60 for ease of passage of the assembly and to reduce the overall amount of tissue that is deflected at one time. Preferably, the dilator is less than 2.5 inches in length, and more preferably, it is less than one inch in length. The maximum radius of a dilator 54 is preferably less than 10 mm, more preferably less than 7.5 mm, even more preferably less than 5 mm. The tip of the dilator 54 is preferably blunt, as, in preferred embodiments, the leading tip of the dilator 54 will pass through tissue that has already been pierced by a needle 60.

**[0178]** The dilator 54 may be made from a variety of biocompatible and sterilizable materials including, without limitation, acetal, Delrin®, Acrylonitrile-Butadiene-Styrene (ABS), polyethylene, nylon and any combination of materials. Alternatively, the sheath 44 may be additionally or solely connected to an end portion of the sling 42.

**[0179]** The dilator 54 preferably includes means for associating with a surgical needle 60. In a preferred embodiment, the association means affords a permanent affixation between the dilator 54 and the needle 60. By "permanent affixation", it is meant that it would be very difficult to manually separate the dilator from the needle after they have become permanently affixed. After implantation of the sling 42, to separate the sling 42 from the dilator 54/needle 60, the surgeon cuts an end of the sling 42 as described more fully below. The association means preferably affords quick and convenient attachment of the dilator 54 to the needle 60 to avoid wasting time in the midst of a surgical procedure. The attachment should also be secure to avoid separation of the needle 60 and dilator 54 while the combination is passed through tissue.

**[0180]** The dilator 54 also includes a means for association with the sling 42 and/or the sheath 44. For example, the dilator 54 may be preattached to the sling 42 and/or sheath 44, particularly if the sling is a synthetic material. Alternatively, the dilator may include means for conveniently attaching to a sling material (e.g. cadaveric or autologous sling material) just prior to sling placement.

**[0181]** Referring to the embodiment of Figures 4A-4E, the dilator 54 may be approximately 3.1 cm (1.2 inches) in length. The dilator 54 preferably includes a gentle taper 88 near its second end 56. The dilator is sized and shaped to provide atraumatic passage through body tissue. The taper 88 and relatively smooth outer surface of the dilator 54 facilitate atraumatic passage of the dilator 54 and attached sling assembly 46 through the various tissues of the patient. The presence of the dilator 54 allows a gentle transition between the diameter of the needle, to the shape of the dilator, and finally to the sling assembly 46, as opposed to prior art assemblies, where the structure of the sling assembly abruptly increases the profile of the needle and thereby the size of the structure that must pass through tissue.

**[0182]** Preferably, the first end 52 of the dilator 54 attaches to one end of the sling 42, or sheath 44 or sling assembly 46 (shown in Figure 4E) and the second end 56 of the dilator 54 may be quickly attached or assembled to a needle 60 (not shown). The sheath 44 is preferably attached to the dilator 54 via a first opening or through-hole 90 located near the first end of the dilator 54. In this embodiment, the opening 90 operates as a universal sling material or assembly attachment

point which can receive a variety of materials, such as fascia, autologous materials, synthetics, biologic tissues and any other similar tissues, including any combinations. The edge portion 91 of one end of the sheath 44 is threaded through the opening 90 of the dilator 54 and secured to the sheath 44, thereby forming a loop 92. The edge portion 91 may be fastened onto the sheath 44 via ultrasonic welding, bonding, melting, suturing, sealing or other attachment techniques. Further, as shown in Figures 4A and 4B, the first end 52 of the dilator 54 includes a cut-away section 94 to provide room to receive sling assembly material to reduce the overall profile of the sling assembly experienced by tissue during sling passage. Therefore, when the sheath is attached to the cut-away section, the additional sheath material is not apt to significantly increase the relative thickness, diameter or profile of the dilator 54.

**[0183]** Alternatively, for dilators 54 manufactured via molding techniques, the end of the sheath 44 may be encased within and secured to the first end 52 of the dilator 54 during the molding process. In yet another embodiment, the end of the sheath 44 may be fixedly attached within a longitudinal slot located near the first end 52 of the dilator 44 using an adhesive, ultrasonic welding or other attachment techniques.

**[0184]** Referring to Figures 4A-4D, the second end 56 of the dilator 54 includes a second opening or through-hole 96 that extends substantially internally along the longitudinal axis of the dilator 54. The second opening 96 has an internal diameter generally configured for convenient attachment to a needle 60 or similar sling-delivery device. In one embodiment, the internal diameter of the second opening 96 of the dilator 54 is approximately within the range of 0.239 cm to 0.318 cm (0.094 inch to 0.125 inch). A shoulder 98 located on the surface 100 of the second opening 96 of the dilator 54 and a complementary mating recess located on the surface of the first end of the needle 60 (see Figure 3) securely and permanently attach or lock the dilator 54 and needle 60 together. Once the needle 60 is inserted into the dilator 54, they are preferably not separated thereafter. After the sling 42 is implanted, the connected needle 60 and dilator 54 are removed from the sling by cutting an end of the sling as described in greater detail below. Preferable, the needle 60 and dilator 54 are disposed.

**[0185]** One or more longitudinal slots 102 located on the outer surface of the dilator 54 and in communication with the second opening 96 allow the wall of the dilator 54 to expand in a radially outward direction when the first end of the needle 60 is inserted into the second opening 96 of the dilator 54. When the shoulder 98 of the dilator 54 passes the recess of the needle 60, the wall of the dilator 54 collapses around the needle 60 as the shoulder 98 seats into the recess, thereby securing the dilator 54 on the needle 60 and blocking separation of the dilator 54 and needle 60.

**[0186]** Although the invention has been described in terms of a shoulder 98 and mating recess, alternative dilator-needle attachment mechanisms such as bumps, grooves, slots, wedges, tabs and other mechanisms are also included within the scope of the claimed invention. The dilator 54 preferably includes one or more relief ports 104 to facilitate convenient needle connection. The relief ports 104 may be formed at the ends of the longitudinal slots 102 or at various high-resistance locations along the dilator 54. The relief ports 104 decrease the rigidity or resistance of radially outward expansion of the dilator wall and, reduce the amount of force required to insert or securely attach the needle 60 to the dilator 54. In yet another embodiment, superficial bands or rings, arc-shaped slots, superficial grooves or other mechanisms may be provided to provide improved expansion or attachment characteristics.

**[0187]** A portion of the dilator 54 includes a taper 88 having a decreasing profile toward the second end 96 of the dilator 54. The taper 88 preferably gently cams tissue out of the path of the sling assembly 46 as the sling assembly is inserted in the body. The taper 88 is also sized and shaped to reduce the amount of friction or resistance as the device is drawn through the tissues of the patient. The amount of force required to manipulate the device through the tissues is thereby reduced. This in turn provides the user of the assembly with additional control over device insertion and maneuverability through tissue and within the patient. In addition to tapered profiles, other dilator profiles such as conical, flared, frusto-conical, pyramid-shaped, elliptical or other applicable profiles may also be used. Overall, the profile of the dilator 54 is preferably configured to provide easy dilation of the tissue to accommodate smooth passage of the sling 42/sling assembly 46 and subsequent collapse of the surrounding tissue to securely anchor the sling 42 into the tissue (after sheath removal).

**[0188]** In other embodiments of the invention shown in Figures 6A and 6B, the dilator 54A or 54B includes a sling fastening snap mechanism 106 on one end of the dilator. The embodiment disclosed in Figure 6A includes a keyed/locking mechanism on its other end. As shown in Figure 6A, the first end of the dilator 54A includes a slot or slot-shaped opening 110 configured for convenient insertion of one end of a sling 42 (such as one made from autologous tissue) or sling assembly 46 either at the surgical site (e.g. by the operating room nurse or surgeon) or other location (such as manufacturing location). Additional shapes for the dilator opening 110 include, without limitation, oval, circular, square, rectangular and other shapes. The slot-shaped opening 110 is located along a portion of the longitudinal axis of the dilator 54A.

**[0189]** Referring to Figure 6B, a snap-like element 112' is located on an outer surface near the first end of the dilator 54B. The snap-like element 112' includes a barb or spike 114 that fits

within an opening 116 situated near the first end of the dilator 54B. The opening 116 for the barb 114, preferably configured perpendicular to the slot-shaped opening 110', is sized and shaped to match or mate with the barb 114 of the snap-like element 112'. When the barb 114 is fully seated within the opening 116 of the dilator 54B, the tip 118 of the barb 114 extends into the slot-shaped opening 110' of the dilator 54B. A first ridge 120 and a second ridge 122 located along the length of the barb 114 further secure and/or fasten the barb 114 within the opening 116 of the dilator 54B. Other fastening configurations including, but not limited to, bumps, shoulders, tabs, detents, tongue in grooves, snaps and any combinations of fastening means may also be used with the present invention.

**[0190]** During use, one end of the sling 42, sheath 44 or sling assembly 46 is inserted into the slot 110' of the dilator 54B. With the end of the sling 42/sling assembly 46 properly positioned within the slot 110', the barb 114 of the snap-like element 112' is inserted into the opening 116 of the dilator 54B. The barb 114 is fully seated within the opening 116 when both ridges 120, 122 pass through the opening 116 of the dilator 54B. This causes the tip 118 of the barb 114 to bear down on or penetrate a portion of the sling 42/sling assembly 46 extending within the slot 110' of the dilator 54B, thereby securely fastening the sling 42/sling assembly 46 to the dilator 54B.

**[0191]** A keyed/locking mechanism 108 is located near the second end 56B of the dilator 54B. As shown in Figure 6B, a square-shaped opening 124 extends along a portion of the longitudinal axis near the second end 56B of the dilator 54B. The shape of the dilator opening 124 matches the square-shaped perimeter of the keying-segment 126 located near the first end 58 of the needle 60 and allows keyed-rotation of the dilator 54B at ninety-degree intervals. Other appropriate shapes for the dilator opening 124 may also be used provided that the shape of the opening 124 complements the corresponding keying-segment shape located near the first end 58 of the needle 60. When the first end 58 of the needle 60 is positioned within the dilator 54B, the square-shaped opening 124 of the dilator 54B together with the keying-segment 126 of the needle 60 prevents axial rotation of the dilator 54B relative to the needle 60 and, thus, twisting of the sling 42/sling assembly 46. This optional feature provides the practitioner or user of the assembly with improved control and maneuverability of the assembly before and during the insertion procedure.

**[0192]** The dilator 54B also includes a locking mechanism 128. Referring to Figure 6B, the locking mechanism 128 comprises one or more tension-loaded ribs located within the longitudinal opening of the dilator 54B. The configuration of the ribs generally matches and corresponds to a complementary recess 130 located near the first end 58 of the needle 60. Thus, the first end 58 of the needle 60 is inserted through the longitudinal opening 124 of the dilator 54B until the ribs of

the dilator 54B seat within the recess 130 of the needle 60. The dilator 54B is securely attached or locked onto the needle 60 when the dilator ribs are fully seated within the needle recess 130. Although the invention has been described in terms of a rib and complementary recess, alternative dilator-needle attachment mechanisms, such as those previously described, are also included herein.

**[0193]** Referring to Figure 7, in an alternate embodiment of the invention, the sheath 44 (or sling 42 or assembly 46) is attached to the dilator 54C via a locking (or compression) collet 132 and adapter connector 134. The compression collet 132 comprises a ring-shaped portion 136 having one or more barbed snap tongs 138. The complementary adapter 134 comprises a cylindrical element 140 having a first end 142 and a second end 144. The internal profile near the first end 144 of the adapter connector 134 includes a tubular lumen or channel 146, having one or more recesses, shoulders, grooves or similar indentations 148, surrounding an internal prong 150. The second end 144 of the adapter connector 134 includes one or more barbed snap tongs 152, similar to the tongs 138 of the compression collet 132. In addition, the first end 52 of the dilator 54C includes a longitudinal opening 154 having one or more recesses, grooves, slots or related types of indentations 156 configured to engage the tongs 152 of the adapter connector 134.

**[0194]** In use, one end of the sling 42/sling assembly 46 of the present invention is configured into a tubular or appropriate shape that enables a sufficient portion of the end of the sling 42/sling assembly 46 to be inserted through the compression collet 132. The tongs 138 of the compression collet 132 are then inserted into the first end 142 of the adapter connector 134, causing the tongs 138 to snap into engagement with the adapter connector 134. The end portion of the sling 42/sling assembly 46 is compressed between the tongs 138 of the compression collet 132 and the internal prong 150 of the adapter connector 134, thereby securely fixing the sling 42/sling assembly 46 to the collet/adapter assembly. In a similar fashion, the tongs 152 of the adapter 134 are then inserted and snap-locked into the first end 52C of the dilator 54C, creating a secure fixation between the collet/adapter assembly and dilator 54C.

**[0195]** Referring to Figure 8A, the needle 60 is generally curved or arcuate. Preferably, the needle is arc-shaped and includes a first end 58 and a second end 62. Although a variety of needle designs and/or configurations may be used including, without limitation, straight, bent, curved, arc-shaped, Stamey, Raz and other configurations, all references hereinafter will be made to an arc-shaped needle in the spirit of brevity and reader convenience.

**[0196]** Overall, the shape of the needle 60 should facilitate and provide controlled passage of the needle 60 through tissue, preferably from an abdominal incision to the vagina or, alternatively, from the vagina to an abdominal incision. The ends or tip of the needle 60 are preferably not sharpened, but may be tapered to afford easy passage through tissue while providing a blunt surface that avoids cutting sensitive tissue such as the bladder or urethra. In a preferred embodiment, the length N of the needle 60 is approximately within the range of 16.5 cm to 24.1 cm (6.5 inches to 9.5 inches) and has a preferred external diameter of approximately 3.175 mm (0.125 inch). It is preferred that the diameter of the needle 60 be small relative to the prior art to reduce tissue trauma.

**[0197]** The needle 60 is made of a malleable, yet durable, biocompatable surgical instrument materials such as, but not limited to, stainless steel, titanium, Nitinol, polymers, plastics and other materials, including combinations of materials. The needle 60 should have sufficient structural integrity to withstand the various forces (e.g. forces caused by dilator attachment, cystoscopy aid passage, and penetration/passage of the needle 60 through the various tissues) without undergoing any significant structural deformation. Optionally, the needles 60 could be sufficiently malleable to allow a practitioner or user of the device to modify the needle 60 to a desired shape and, thereby, optimize the procedural approach.

**[0198]** As shown in the embodiment of Figure 8A, the first end 58 and second end 62 of the needle 60 may include a keying feature 170 affording secure association between the needle and handle 64 and/or dilator 54 and/or sheath assembly 46. In one embodiment, the keying feature 170 comprises a recess 130 and/or square-shaped portion 126. As previously described, the recess 130 and square-shaped portion 126 are designed for complementary engagement to the appropriate end of a dilator 54 or handle 64. Another embodiment of the invention includes a reversible keying feature. The reversible keying feature allows the handle 64 to be interchangeably attached yet securely affixed to either end of the needle 60. In a preferred embodiment, the needle 60 may be substantially symmetric about a centerpoint, that is, the radius of curvature of the needle 60 may be substantially constant and either a handle or a dilator may be attached to either end of the needle 60.

**[0199]** In an alternate embodiment, the keying feature of the needle 60B comprises an end cap 172 and an elongate reduced width segment 174 having a square-shaped cross sectional profile, as shown in Figures 16B to 16D. The second end 62B of the needle 60 shown in these Figures is inserted into the keying feature or channel 176 that extends along the longitudinal axis of the handle 64B (partially shown in Figures 8D to 8F). When the needle 60B is properly positioned

within the handle 64B, a yoke or other fastening component 178 receives and secures the elongate segment 174 in the narrow portion 180 of the channel 176, as shown in Figures 8D and 8E. The complementary configuration of the channel's narrow portion 180 and the needle's elongate segment 174 prevents the handle 64B from rotating around the axis of the needle 60B. In addition, this configuration may also provide additional needle/handle stability and improved tactile feedback for a user of the device.

**[0200]** The present invention may optionally include structure that allows the surgeon to change the orientation or position of the handle relative to the needle. The handle may be rotatably repositioned relative to the needle or, in some embodiments, the handle may be axially slidable and repositionable along the length of the needle. The handle may be repositioned in any orientation as determined by the surgeon or it may be indexed between a plurality of predetermined orientations depending on the particular embodiment of the present invention.

**[0201]** Figure 8E illustrates the needle seated in a locked position relative to handle 64B. In order to rotate the handle 64B, a user or practitioner manipulates a trigger or button that actuates the fastening component 178 thereby causing the channel 176 to disengage from the elongate segment 174, as shown in Figure 8F. In this position, segment 174 of the needle 60B is no longer seated in the handle 64B. With the elongate segment 174 positioned in the wider portion 182 of the channel 176, the needle 60B is free to rotate. However, the configuration of the needle's end cap 172 prevents the needle 60B from becoming completely disengaged from the handle 64B. Thus, the keying features maintain the needle 60B in proper alignment with the handle 64B when in the locked position and also allow a user to controllably rotate the needle 60B to obtain a desired handle 64B orientation.

**[0202]** In another embodiment, the handle 64 may be permanently attached to an end 62 of the needle 60. More particularly, the handle 64 may be rigidly affixed to the needle 60 so that substantially no relative movement may occur between the needle 60 and the handle 64.

**[0203]** Referring to Figure 9A, one embodiment of the adjustable handle 64G comprises a relatively smooth, ergonomic body made of delrin, ABS, nylon, polycarbonate, acetal, polyetherimide, polysulfone or other sterilizable materials. The body of the handle 64G may be hollow, solid or semi-solid. One or more surfaces of the handle include a plurality of ridges 190 and/or indentations 192 that provide an enhanced gripping surface for a user of the device. Alternatively, various portions of the surface of the handle 64G may also include grasping features such as bumps, grooves, ridges or other gripping means, that enable improved manipulation of the

handle 64G. In addition, the handle 64G may include an indentation formed near the middle 194 of the handle 64G that provides a user of the device with better control of, and an improved grip on, the handle 64G.

**[0204]** A push button 198 and keyed opening 200 are located near the needle attachment end 196 of the handle 64G shown in Figure 9A and form a keying feature of the handle 64G. As shown in Figure 9B, the push button assembly 198 comprises a button or knob-shaped component 202 that attaches to a yoke 204 (attachment locations indicated by dashed reference line). In particular, the yoke 204 is attached to the button 202 via snap tongs 206 that lock the button 202 and yoke 204 together. Prior to attachment, the button 202 and yoke 204, including a spring 208, are fitted within their respective grooves and/or slots formed near the needle attachment end 196 of the handle 64G, as generally shown in Figure 9C. The spring 208 provides the appropriate tension to maintain the assembly in a locked position.

**[0205]** When the assembly is in a locked position (shown in Figure 9D), the spring forces push the button 202 in a direction away from the longitudinal axis of the device. This in turn causes the groove or recess 210 of the attached yoke 204 to protrude within the keyed longitudinal opening 200 resulting in a non-square-shaped opening formed along an axial portion near the needle attachment end of the handle 64G. In the locked configuration, the handle 64G is securely attached in a stationary position on the needle 60. Pressing or pushing the button 202 inwardly toward the axis of the device unlocks the device and creates a square-shaped or keyed opening 200 for the needle 60. Figure 9E illustrates a cross-section of the keyed, longitudinal opening 200 in an unlocked position.

**[0206]** The quick-release push button of the handle 64G enables a user of the device to easily attach or detach the handle 64G from the needle 60 or reposition the orientation of handle 64G relative to the needle 60, using one hand. While gripping the handle 64G, the user of the device simply depresses the push button 202 with one finger to unlock the handle. Still using a single hand to control the handle 64G, the user can then insert one end of the needle 60 into the keyed opening 200 of the handle 64G and, upon releasing the button 202, secure the handle 64G to the needle 60.

**[0207]** As previously disclosed, the needle 60 includes a similar keying feature configured for complementary engagement with the keyed portion of the handle 64G. These complementary, square-shaped keying features allow a practitioner or user of the device to rotatably index the handle 64G between predetermined positions located in ninety-degree increments around the

needle axis. Thus, the practitioner may position the handle 64G in a preferred configuration on the needle 60 that provides the greatest comfort and ease of insertion. In addition, via the locking mechanism, the keying features also prevent the handle 64G from uncontrollably rotating around the axis of the needle 60, for instance, during a sling or needle insertion procedure. Although the invention has been described with respect to a square-shaped keying feature, other geometrical configurations and keying means are also included within the scope of the present invention.

**[0208]** Another embodiment of needle attachment mechanism for a handle is shown in Figures 10A to 10C. The handle 64H includes a quick-release feature 212 comprising one or more levers 214 and an associated border or frame 216 that surrounds an opening 218. The opening 218 is generally located near the needle end of the handle 64 and along the longitudinal axis of the device. The frame 216 bordering the opening 218 may include various indentations or ridges 220 that provide improved gripping capabilities. In addition, the handle may also include a square-shaped keying feature 222 similar to the previously described keying features. A different shaped handle 64I is shown in Figures 10B and 10C.

**[0209]** During use, a practitioner or user of the device simply compresses the levers 214 of the handle 64H together using, for example, a thumb and forefinger. Compression of the levers 214 changes the configuration of the frame 216 and opening 218 to allow insertion of a needle 60 therein. The user of the device releases the levers 214 when the needle 60 is properly positioned within the handle 64I, causing a portion of the frame 216 to compress against a portion of the needle 60 (e.g., a recessed portion) thereby blocking axial movement of the needle relative to the handle 64I and securely attaching the handle 64I onto the needle 60. The handle 64I can be quickly released from the needle 60 by pressing on the handles 214.

**[0210]** Another embodiment of a quick-release feature for the handle 64K is shown in Figures 11A-11C. For this embodiment of the invention, the handle 64K may be made from a single molded or machined component. A quick-release button 224, located near the needle end of the handle 64K, controls a keyed needle-latching mechanism 226. As best seen in Figure 20B, the needle latching mechanism 226 generally includes a geometrically shaped opening section 228, a locking section 230 and an end section 232. When a practitioner or user of the device depresses the quick-release button 224, the semi-resilient material of the handle 64K causes displacement of the locking section 230, thereby allowing the needle 60 (not shown) to be inserted into the latching mechanism 226 of the handle 64K. After the needle 60 and handle 64K are positioned or aligned according to user preference, the button 224 is released causing the locking section 230 to return to its initial configuration and, in so doing, seat within the complementary, recessed feature of the

needle 60. This not only secures or locks the handle 64K onto the needle 60 but also prevents the handle 64K from rotating around the needle axis.

**[0211]** In another embodiment of the invention, the keyed, locking portion and/or quick release feature of the handle 64K may be located near the middle of the handle 64K, near the end of the handle 64K close to the needle (figure 9A) or at any preferred location on the handle 64K. A large or small section or length of the needle 60 may be housed within and contact the handle 64K of the device, thereby providing enhanced user-control and stabilization of the needle 60 relative to handle 64K. The increased surface contact between the needle 60 and handle 64K may also strengthen the associated gripping or frictional forces, resulting in improved locking or attachment capabilities of the device.

**[0212]** The associated quick-release feature (such as push button 198, button 224, levers 214, etc.) may also be positioned at any preferred location on the handle 64 of the present invention. For example, referring to Figures 12A and 12B, positioning the button 202 opposite to the needle insertion end 196 of the handle 64L may reduce or prevent accidental triggering of the button 202. Further, this particular design may provide additional ergonomic advantages for the user of the device. For example, the bottom could be flush or recessed with the surface of the handle.

**[0213]** Various configurations of the overall size, weight and shape of the handle 64 are also included within the scope of the claimed invention. Still referring to Figures 12A and 12B, another embodiment of the handle 64L comprises a compact profile. The smaller size of the handle 64L reduces the weight of the handle 64L, thereby making the device 40 less heavy at the top and better balanced. Alternatively, the handle 64L may also be configured to be permanently, but rotatably, affixed to the needle 60 (not shown). As such, the user or practitioner may rotate the handle 360° around the axis of the needle 60 and lock the handle 64L in position once the desired orientation is reached.

**[0214]** Figure 5 illustrates an alternate embodiment of the present invention that includes a slidable second handle 64' which may be used alone or in combination with handle 64. In general, the slidable handle may provide additional ergonomic advantages and control during the needle insertion procedure. For example, when used in combination with the handle 64, the slidable handle 64' is initially positioned and optionally locked near the first end 58 of the needle 60. During needle insertion (further described below), the slidable handle allows the user or practitioner to maneuver the needle 60 more accurately along the insertion pathway. In the example of an initial suprapubic approach, after the slidable handle 64' comes close to or in

contact with the abdomen, the slidable handle 64' is unlocked and repositioned closer to the handle 64. The slidable handle is then secured at the new position and locked in place, thereby allowing further insertion of the needle 60.

**[0215]** The second handle 64' may optionally be locked in a position that blocks inadvertent lurching of the needle 60 within the tissue. Preferably, the second handle 64' is sized and shaped to engage the abdominal tissue to act as a stop to prevent further penetration of the needle 60 until the second handle 64' is unlocked and moved to a location closer to the handle 64. This feature is believed to be useful in resisting uncontrolled passage of the needle 60 into the retropubic space after the end 58 of the needle 60 bursts through the tough rectus fascia. Once the rectus fascia is penetrated, the second handle 64' is unlocked and moved to a location closer to the handle 64 and the needle can be controllable passed through tissue.

**[0216]** Optionally, the second handle 64' may include means for affording sliding of the handle 64' toward the handle 64, but that resists movement of the handle 64' away from the handle 64. The means may comprise a plurality of ribs within handle 64' that engage the needle 60 and that are angled toward the handle 64.

**[0217]** Referring to another embodiment shown in figures 13A and 13B, a slidable handle 204 comprises a body portion 206 (partially shown in Figures 13A and 13B), latch 208, o-ring 210 and spring ring 212 contained in a handle cavity 207. In general, the body portion 206 and latch 208 may be made of delrin, ABS, nylon, polycarbonate, acetal, polyetherimide, polysulfone, or other sterilizable materials. In addition, the o-ring 210 and spring ring 212 may be made from high durometer polyurethane, teflon and other rigid or semi-rigid materials.

**[0218]** The frustro-concially shaped spring ring 212 comprises a first end 214, a second end 216 and a lumen 218. In general, the external diameter of the first end 214 of the spring ring 212 is greater than the external diameter near the second end 216 of the spring ring 212, thereby forming an inclined surface. The lumen 218, situated along the axis of the spring ring 212, is configured to slidably engage a needle 60.

**[0219]** Located adjacent to the spring ring 212 is a frusto-cylindrically shaped o-ring 210. The o-ring 210 comprises a first end 220, a second end 222 and a lumen 224 having a first surface 226 and a second surface 228. The first surface 226 of the lumen 224 is located near the first end 220 of the o-ring 210 and forms an incline configured for complimentary engagement with the inclined

surface of the spring ring 212. In contrast, the second surface 228 of the lumen 224 is located near the second end 222 of the o-ring 210 and is designed to slidably engage the needle 60.

**[0220]** Adjacent to the o-ring 210 is a latch 208 comprising two posts 230 and two tabs 232, wherein similar ends of each post 230 are attached to a tab 232. In addition, the posts 230 border the needle 60 in perpendicular alignment with the needle axis, thereby forming, together with the tabs 232, a frame around a portion of the needle 60. One end 234 of each post 230 also includes a flange 236 that triggers the locking mechanism of the handle 204. The handle 204 is locked onto a needle 60 by depressing a tab 232 so that the flange 236 contacts a portion of the o-ring 210 and causes the o-ring 210 to engage the spring ring 212. The force of the o-ring 210 against the spring ring 212 compresses the longitudinal length and causes radial expansion and compression of the spring ring 212, thereby generating frictional forces among the spring ring 212, needle 60 and handle cavity 207. These frictional forces prevent needle movement in the longitudinal direction (i.e. along the needle axis). To prevent handle 204 rotation on the needle 60, a projection 238 may be formed on an external surface of the o-ring 210 and configured for complimentary engagement with an indentation 240 formed on an internal surface of the handle 204. Further, the handle 204 may be unlocked in a similar fashion by simply depressing the other tab 208 and, thereby, releasing the compressive forces which causes the components to disengage.

**[0221]** Figure 13B illustrates an embodiment of lockable handle similar to that of Figure 13A. Elements in Figure 22B have been given reference characters similar to those of Figure 13A, to which the suffix "B" has been added.

**[0222]** Referring to Figures 14A-14C, an alternate embodiment of the slidable handle comprises a body portion, o-ring 212, spring ring 210 and slider 242 contained in a handle cavity. The o-ring 210 and spring ring 212 of this embodiment of the slidable handle 204 are similar to those previously described. However, the cylindrically shaped o-ring 210 includes at least one rod 244 extending perpendicular to the needle axis and partially projecting from the cylindrical surface of the o-ring 210.

**[0223]** The slider 242 of the handle 204 comprises two shafts 246, that pivot on a rod (not shown) about a pivot point 248, and a switch 250. In general, the shafts 246, switch 250 and rod 244 may be made from substantially the same materials, such as delrin, ABS, nylon, polycarbonate, acetal, polyetherimide, polysulfone or other similar materials. The first end 252 and second end 254 of each shaft are configured to securely engage the switch 250 and rod 244, respectively, thereby

forming the slider assembly. The slider 242 in combination with the o-ring 219 and spring ring 212 are the mechanisms by which the needle 60 and handle 204 may be locked and unlocked.

**[0224]** For example, a user locks the handle 204 by pushing or pressing the switch 250 in one direction. This action causes the shafts 246 to move the o-ring 210 into complementary engagement with the spring ring 212. As previously described, the resulting frictional forces prevent linear displacement of the needle 60, thereby securely locking the handle 204 onto the needle 60. The handle 204 may be unlocked by simply pushing the switch 250 in the opposite direction.

**[0225]** In another embodiment, shown in Figures 15A-15D, the slidable handle comprises a body portion 206, upper block 256, lower block 258, load distributor 260 and force providing member 262 (e.g. a cam). The body portion 206 of the handle 204 may be made of materials similar to those described in previous embodiments. In addition, the lower and upper blocks 258, 256 may be made of high-density polyurethane, whereas the load distributor 260 and force providing member 262 may be made of a material with a high coefficient of friction.

**[0226]** Referring to Figures 15A-15C, the generally square-shaped blocks 256, 258 include a channel 264 formed within a portion of each block. The channels 264 are configured to house a needle 60 when the blocks 256,258 are properly aligned within the handle body 206. In addition, ridges, bumps, or other similar gripping features are formed on the surface of each channel 264 to enhance the needle gripping capabilities of the blocks 256,258.

**[0227]** The handle of Figures 15A-15E locks onto a needle 60 by depressing the force providing member 262. The force providing member 262 forces the upper block 256 into close proximity with the lower block 258, subsequently compressing or sandwiching the needle 60 therebetween. The compression forces, which are evenly displaced via the load distributor 260, together with the gripping surfaces of the blocks 256,258 prevent linear displacement of the needle 60 relative to the handle when locked within the handle body 206, as shown in Figure 15D. Although the gripping features should sufficiently prevent the handle body 206 from rotating about the needle axis, additional keying features may also be added. For example, the needle 60 and needle lumen 268 of the handle body 206 may include complementary features, such as flattened surfaces 270 shown in Figure 15E, that provide added stability to the present invention.

**[0228]** Referring to Figure 16, an alternate embodiment of the locking mechanism of the slidable handle 204 comprises an upper clamping block 272, lower block (not shown), two cams 276, a rod

278 and two pins 280. The needle is designed to be placed between the upper and lower blocks and sandwiched therebetween. Rotation of the wheel cams 276 provide balanced pressure on clamping block 272.

**[0229]** In another embodiment of the present invention, the slidable handle 204 comprises a body portion 206 and locking mechanism 282. The body portion may be made from silicone rubber or other elastomeric materials. As shown in Figure 26, the body portion 206 includes a barbed inner lumen 284 that functions as the locking mechanism for the needle 60 (not shown). As such, the orientation of the barbs prevent the slidable handle 204 from sliding in one direction along the needle 60 (e.g. toward the end of the needle that is placed in the tissue), yet permit the handle 204 to slide in the opposite direction along the needle 60. This allows the practitioner to use the slidable handle 204 to control or guide the needle 60 through tissue and also reposition the slidable handle along the length of the needle 60.

**[0230]** Another embodiment of the locking mechanism is shown in Figure 18. This mechanism is similar to the embodiment of the locking mechanism referenced in Figures 15A-15E. However, instead of depressing a cam 262, a user depresses a button 286 that latches into a mating release element 288. Yet another embodiment of a locking mechanism, shown in Figure 28, comprises a screw-like device 290 that can be locked and unlocked simply by twisting or rotating a portion of the device 290. Other embodiments of locking mechanisms are also included within the scope of the claimed invention.

**[0231]** In another aspect, the present invention comprises a kit for treating a patient (e.g. for SUI). The kit preferably comprises at least two needles, an implantable material for supporting structure and at least two dilators. Two or more needles reduces the need to reuse a needle at a different location with a patient, thereby eliminating cross contamination issues. Additional needles, dilators and other elements may also be included for surgical convenience, for avoidance of contamination from one portion of the body to another, for ease of manufacturing or sterilization or for surgical requirements. For example, four needles may be utilized to implant the sling of Figure 41. The needles would pass through abdominal incisions and through a vaginal incision.

**[0232]** Optionally, the sling 42 may includes a means for determining the tension in the sling. The tension determination means may comprise an element attached to the sling or incorporated in the sling that is capable of measuring sling tension.

**[0233]** The elements of the assembly of the present invention may be any color. Preferably, the elements are of constructed to be a color that contrasts with the intended physiological environment and with other elements. For example, the sling 42 is preferably white and the position adjustment member 66 may be blue. This helps the surgeon identify the location and discern the elements of the assembly.

**[0234]** Examples

**[0235]** Many methods are contemplated herein. Although the methods of use as disclosed herein generally relate to female incontinence conditions and treatments/procedures, male incontinence conditions and treatments/procedures are also included within the scope of the present invention. Procedures that address problems other than incontinence (e.g. cystocele, enterocele or prolapse) are also contemplated alone or in conjunction with the present invention. Further, the term "urethra," with respect to sling positioning, is used for brevity and reader convenience. It should be noted that the present invention is particularly suitable for placing a sling in a therapeutically effective position. The method may be utilized to support a variety of structures at different anatomical locations. As such, the terms "target site," "bladder", "urethro-vesical juncture", "vaginal vault", "U-V juncture" and "bladder neck" are also included within the scope of the present invention.

**[0236]** Referring now to figures 20A through 21C, a preferred embodiment of surgical procedure for treating female incontinence is disclosed according to an aspect of the present invention. Initially, the patient is placed under local, spinal or general anesthesia. A small transverse incision 404 is made in the anterior vaginal wall 20 of a female patient followed by a transurethral dissection. Two small transverse suprapubic abdominal stab incisions 400 are also made near the back of the pubic bone (e.g. each about 1 cm from the midline, or alternatively, one large incision may be made) to allow for needle entry. Optionally, two paraurethral dissections (incisions next to the urethra) lateral to the midline may be created to allow the surgeon's finger to meet the end 58 of the needle 60 during the procedure.

**[0237]** A handle 64 is optionally adjusted relative to needle 60 according to surgeon preference and securely associated with the second end 62 of the needle 60. Optionally, the attachment and configuration of the needle-handle assembly may be adjusted or customized to user preference. The handle 64 may be optionally released from the needle 60 by pushing a button or compressing levers located on the handle 64. Once released, the handle 64 can then be rotated or displaced along an axis of the needle 60 to a preferred position. After the handle 64 is properly positioned

on the needle 60, the button or levers are released, thereby causing the handle 64 to become securely attached to the needle 60.

**[0238]** Figure 20A shows the second end 58 of needle 60 just passing an abdominal incision 400. Preferably, after the second end 58 of the needle 60 passes the suprapubic abdominal incision 400, the surgeons seeks to encounter resistance associated with the posterior portion of the patient's pubic bone 402 with the second end 58 of the needle 60 to controllably move the end 58 of the needle toward the vaginal incision 404 and to help avoid damaging structures such as the urethra and bladder of the patient. The second end 58 of the needle 60 is used to identify the location of the pubic bone 402. The surgeon exploits the resistance provided by the pubic bone 402 to controllably pass the end of the needle 58. This approach is preferred as it helps keep the needle 60 away from major pelvic vessels, nerves and anatomical structures such as the urethra, bowels and bladder.

**[0239]** Figure 20B illustrates the end of the needle as it just passes the suprapubic incision. Figure 20C illustrates the needle 60 as the surgeon experiences the tactile feel of the resistance provided in part by the posterior portion of the pubic bone 402. Figure 20C shows the needle 60 as it passes in proximity to the posterior surface of the pubic bone 402 which continues to operate as an anatomical guide for the surgeon as the needle end 58 approaches vaginal incision 404 (see Figure 20D).

**[0240]** Figure 21A is a schematic end view generally illustrating regions to avoid 390 during the surgical procedure and preferred passage region 385. Deviation of the end 58 of the needle 60 outside of the preferred passage region 385 into the regions to avoid 390 is believed to increase the potential for damaging arteries, veins, organs, lymph tissue and other tissues that are likely to lead to complications. Passing the needle 60 in the preferred passage region 385 avoids contact between the end of the needle 58 and these structures.

**[0241]** Figure 20D illustrates the needle as it passes out of a vaginal incision 404. The surgeon typically holds the handle 64 of the needle 60 during this time by using predominantly one hand. Optionally, with the index finger of the opposite hand, the surgeon may meet the end 58 of the needle via the paraurethral dissection. The surgeon's finger may be delicately placed adjacent endopelvic fascia of the patient and used to guide the needle 60 through the relatively tough endopelvic fascia and into the vaginal incision 404. This helps the surgeon keep away from structures such as the bladder, urethra and other sensitive tissue.

**[0242]** The small diameter and curvature of the needles 60 help to provide precise passage of the needles 60 to the vaginal incision 404. In addition, this needle configuration creates a minimally invasive pathway through tissue extending between the abdominal wall and pubic space, thereby reducing the risk of perforating the bowel and/or blood vessels and nerves located lateral to the bladder 14.

**[0243]** The steps described above are repeated as needed for a second needle 60 on the other side of the urethra 16. Figure 21B is a schematic end view showing two needles placed in a patient and ready to receive a sling or sling assembly. Once both needles are placed, surgeons typically perform a cystoscopy to ensure that the bladder is not punctured before implanting the sling. A cystoscopy confirms the integrity of the bladder 14 and urethra 16 or recognizes a bladder perforation.

**[0244]** Figure 21C is a perspective view of a sling system associated with two needles 60. To attach the sling assembly, the plastic sheath 44 is oriented so that the optional center orientation indicia (e.g. a blue mark) is facing away from the surgical field, toward the surgeon. The dilators 54 are then pushed onto the ends 58 of needles 60 as shown in Figure 21C. The dilators 54 are preferably snapped irreversibly into place for a secure connection. Also preferably, the dilators 54 are connected to the needle in a fashion that prevents rotation of the dilators 54 relative to the needles 60.

**[0245]** Returning to Figure 21C, before snapping the second dilator 54 onto the second needle 60, the surgeon determines that the majority of any optional adjusting filament 66 is facing away from the urethra 16, and that the sling mesh is untwisted.

**[0246]** Dilators 54, including a pre-attached sling assembly 46, are attached to the first ends 58 of the needles 60 protruding from the vagina 20. As discussed above, after the first dilator 54 is attached to one needle 60, the sling assembly 46 is properly oriented so that the sling assembly 46 is not twisted prior to attaching the second dilator 54 to the end of the other needle 60. In addition, the sling assembly 46 is oriented so that the larger filament loops (of the position adjustment member 66) are facing outward or away from the urethra 16. After the dilators 54 and sling assembly 46 are properly positioned, the dilators 54 are securely attached to the needles 60 to ensure that they do not become detached as the needles 60 are preferably pulled simultaneously through the tissues of the patient.

**[0247]** Once the dilators 54 are securely attached, the needles are pulled up through the suprapubic incisions as shown by the arrows in Figure 21C, taking care to avoid contact with sensitive tissue. The sling is then clamped with surgical clamps (not shown). Preferably, the handles 64 are used to pull the needles 60 up through the suprapubic incisions 400. During this portion of the process, the attached dilators 54 and sling assembly 46 are atraumatically pulled up through the needle paths, advancing the sling assembly 46 adjacent to and looped beneath the urethra 16 or target site. A portion of each end of the sling assembly 46 extending beyond the suprapubic incisions 400 is clamped and then cut to release the needles 60 and attached dilators 54.

**[0248]** The sling is placed in a therapeutically effective position. The precise anatomical position will depend upon a variety of factors including the type and degree of anatomical damage or insufficiency, whether the sling procedure is combined with other procedures and other surgeon decisions. Typically, the sling is placed midurethra, without tension, but in position to support the midurethra. Alternatively, the sling could be placed to support the bladder neck and/or UV junction.

**[0249]** Once the sling assembly 46 is carefully positioned under the midurethra or target site to provide sufficient support to the target site, the overlapping portion of the sheath 44 located near the center of the sling assembly 46 and the axially located member 66 (i.e. tensioning filament) may then be used to center and properly position the sling assembly 46 under the midurethra. The sheath 44 is then removed.

**[0250]** Referring to the alternate embodiment shown in Figure 22, a small incision is made in the perineal area 406 of a male patient. As with the female patient, two small transverse suprapubic incisions 400 are also made to allow for needle entry. After the handle 64 is securely attached and properly positioned on the needle 60, the first end of the needle 60 is passed through one of the suprapubic incisions 400, down the posterior side of the pubic bone 402, through the endopelvic fascia and into the perineal incision 406. The user of the device utilizes the handle 64 to guide the needle 60 through the various tissues, avoiding major pubic vessels, the bladder 14 and prostate gland. The second needle 60 is inserted in a similar fashion on the contra-lateral side. A cystoscopy procedure may be performed to confirm bladder integrity. The dilators 54 and sling assembly 46 are then positioned under the target site, sling tension is adjusted and the remainder of the procedure is performed similar to that previously described for a female patient.

**[0251]** In an alternate embodiment, the slidable handle 204 is used in place of or in combination with the handle 64. As previously described, the slidable handle 204 is positioned in a locked

configuration near the first end 58 of the needle 60 and handle 64 is positioned near the second end 62 the needle 60. The repositionable handle 204 may be used as a stop to prevent inadvertent lurching of the needle 58 into sensitive tissue. As the needle 60 is inserted into the incision, the user or practitioner pushes the needle 60 through the incision 400 using handle 64 and guides or maneuvers the needle 60 through the various tissues and spaces using slidable handle 204. When the slidable handle 204 comes in close proximity to the incision, the user unlocks the handle 204 and slides the handle 204 along a length of the needle 60. The slidable handle 204 is thereby repositioned away from the incision and closer to the first end 62 of the needle 60. Once properly located, the slidable handle 204 is then locked in place and the insertion procedure continues. The unlocking, repositioning and locking actions are repeated at the convenience and discretion of the surgeon until the needle 60 is fully inserted. Thus, this embodiment provides a system with more controlled and precise maneuverability than prior art structures.

**[0252]** In another embodiment of the invention, shown in Figures 23 through 25, one end of the needle 60 is initially passed through a vaginal incision 404 and toward one of the suprapubic incisions 400. While inserting the needles 60 initially through the vagina is not preferred, it is within the scope of the present invention as some surgeons may prefer this approach due to previous surgical training, custom or personal preference. The handles 64 are used to push and precisely guide the needle 60 through the various tissues, without perforating or damaging the bowel and/or blood vessels. With the first needle 60 in place, a second needle 60 may be inserted in the same way on a contra-lateral side. As before, a separate cystoscopy procedure may be performed to confirm bladder integrity.

**[0253]** As shown in Figure 24, the handles 64 are detached from one end of the needles 60 and securely attached at the opposite ends of the needles 60 protruding from the abdominal incision 400. In this configuration, a user of the device can use the same handles 64 to also withdraw the needles 60 from the patient. Alternatively, the first pair of handles 64 can be detached from the needles 60 protruding from the vagina and discarded. A second pair of new or different handles 64 can then be attached to the needles 60 protruding from the abdominal incision 400 and used for the remainder of the procedure.

**[0254]** Referring to Figure 25, the dilators 54 and sling assembly 46 are attached to the ends of the needles 60 protruding from the vagina 20. The remainder of the procedure is similar to that described in previous embodiments of the invention.

**[0255]** In another example, four needles may be utilized to implant the sling shown in Figure 26. The needles may extend from four abdominal incisions to a vaginal incision. The sling 42P may be used as a hammock to support the bladder or for other procedures to address a cystocele or prolapse or a vaginal vault treatment.

**[0208]** The following description is meant to be illustrative only and not limiting. Other embodiments of this invention will be apparent to those of ordinary skill in the art in view of this description.

**[0209]** Referring to Figure 3, an embodiment of assembly 40 ~~in accordance with the present invention~~ includes a sling assembly 46 that includes a sling 42 for treating incontinence. The present invention is particularly suitable for treating stress urinary incontinence (SUI) diagnosed with urethral hypermobility or intrinsic sphincter deficiency in both men and women. Although the invention as disclosed herein generally refers to SUI, treatment of other urological disorders, such as urge incontinence, mixed incontinence, overflow incontinence, functional incontinence, prolapse (e.g. vaginal), enteroceles (e.g. of the uterus), rectoceles and other non-urological disorders, are also included within the scope of the present invention. It is contemplated that the present invention may also be utilized in conjunction with other procedures, such as, but not limited to, procedures for addressing cystocele prolapse, vaginal prolapse and anatomic hypermobility.

**[0210]** The sling assembly 46 preferably includes an implantable member (e.g. a hammock, sling or strip) 42 within a protective sheath 44. The sheath 44 is used during insertion of the strip 42. After the sling 42 is implanted, the sheath 44 is removed and discarded.

**[0211]** Each of the two ends 48, 50 of the elongate sling assembly 46 attaches to a first end 52 of a dilator 54 or needle-sling connector. The dilator 54 dilates a needle track for ease of sling introduction and positioning within the patient. A second end 56 of each dilator 54 is sized and shaped to quickly and securely connect to a first end 58 of a slim, arc-shaped needle 60. An adjustable handle 64 is preferably removably and repositionably attached to a second end 62 of the needle 60. Each end 58, 62 of the needle 60 is preferably keyed to allow for convenient, secure attachment of the needle 60 relative to the handle 64 and dilator 54. In a preferred embodiment, the key feature prevents rotation of the dilator 54 relative to the needle 60. Alternatively, the handle 64 may be rigidly affixed to the needle 60.

Details about the sling, the sheath, the tension adjustment member 66

**[0212]** ~~Referring to Figures 1 and 1A, the sling 42 preferably comprises first and second major surfaces, a pair of end portions I, and a support portion II for placement in a therapeutically effective position relative to a physiological environment intended to be supported (e.g. near the urethra). In one aspect of the present invention, the sling 42 preferably has a tension adjustment or control member 66 associated with the sling 42, for transferring sling adjustment forces from one portion of the sling 42 to other portions of the sling 42 such as the ends 61 of a support portion II.~~

can be found in EP-A-1 353 598.



→ page 23

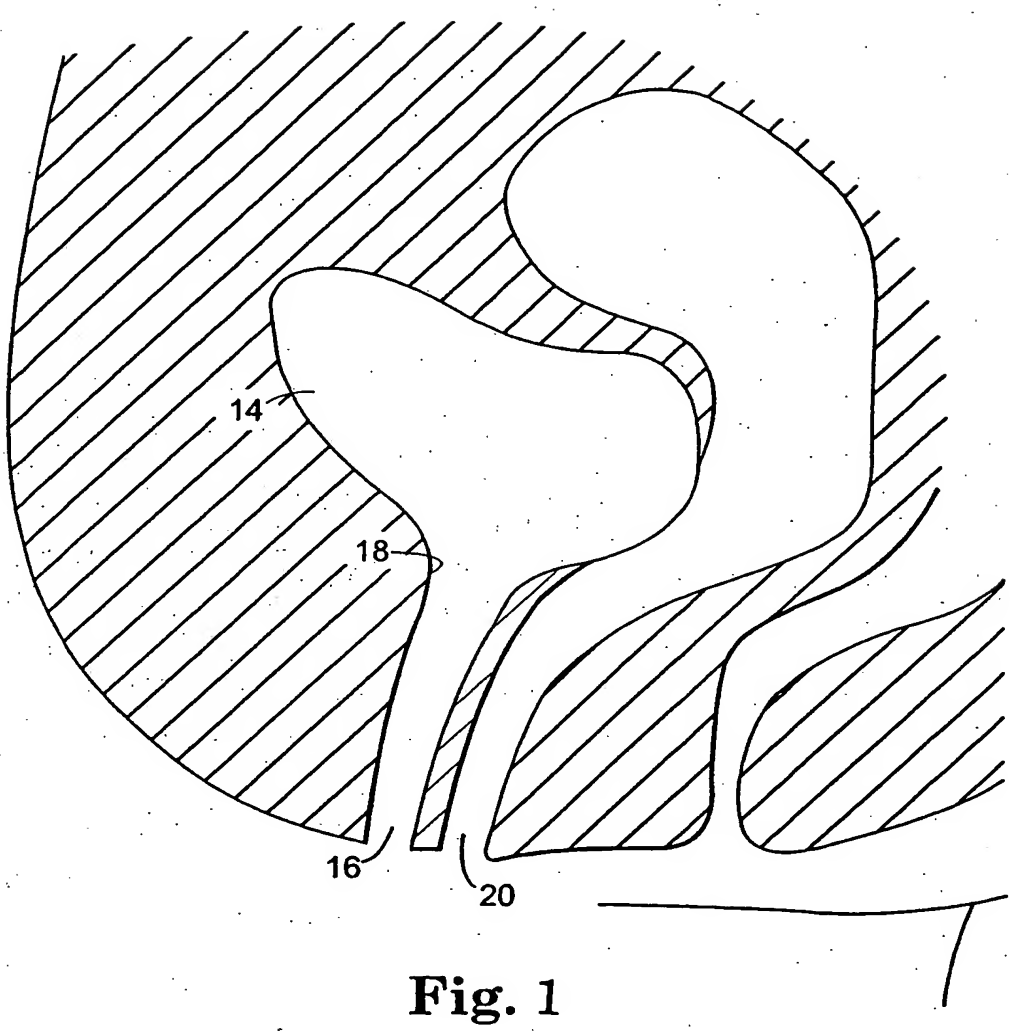


**Fig. 1**

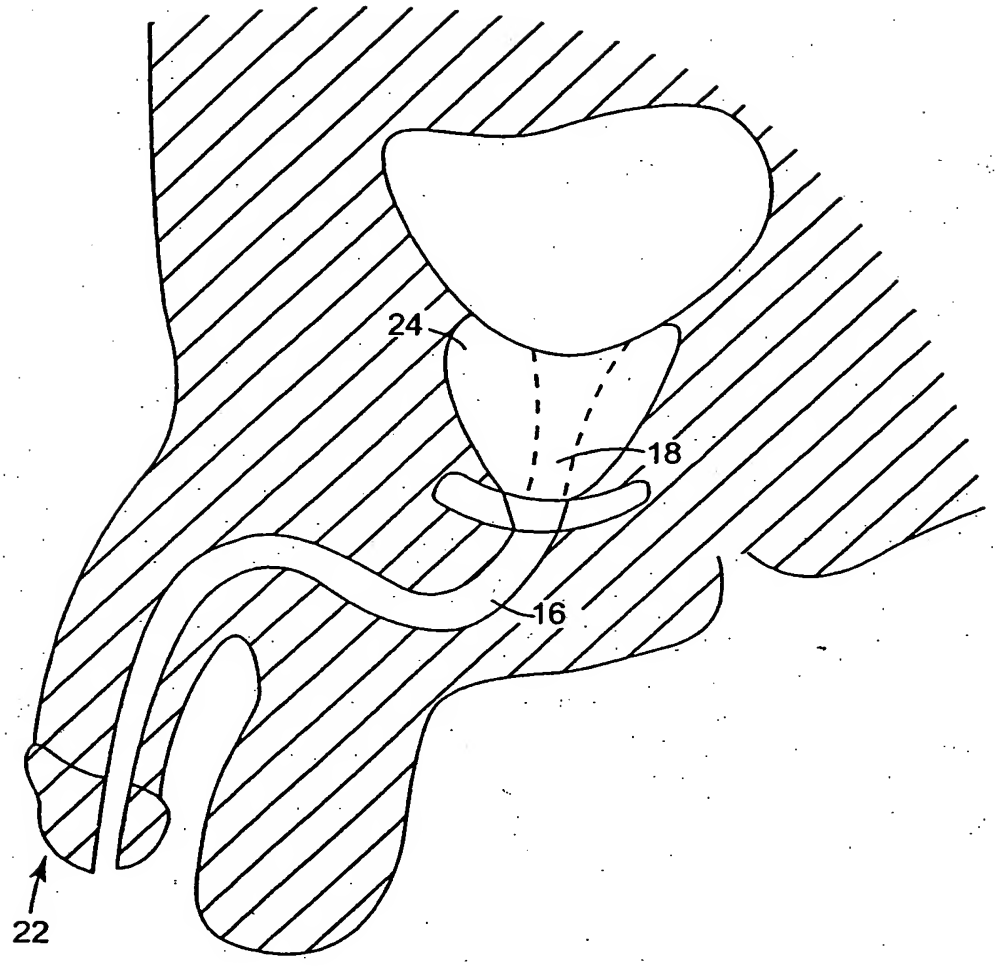


**Fig. 2**

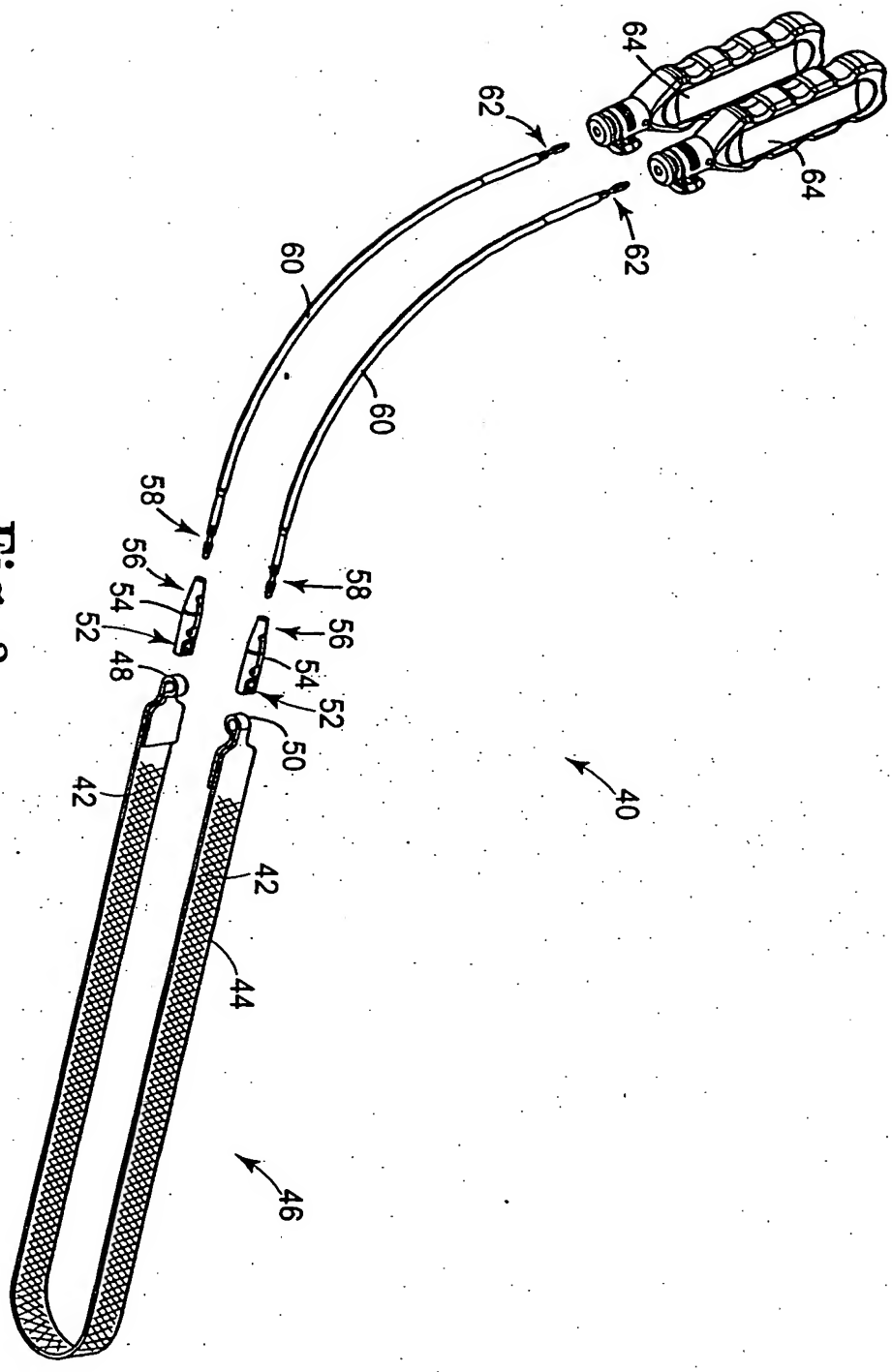


Fig. 3

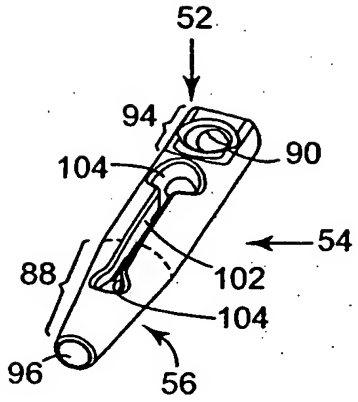


Fig. 4A

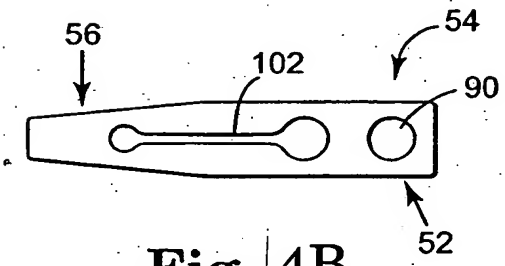


Fig. 4B

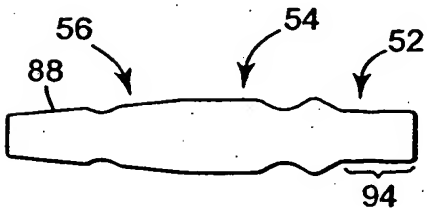


Fig. 4C

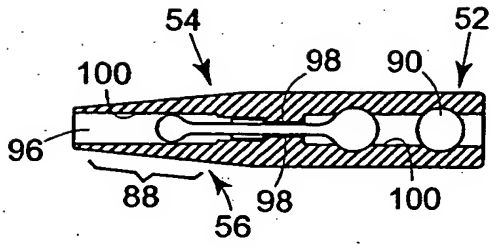


Fig. 4D

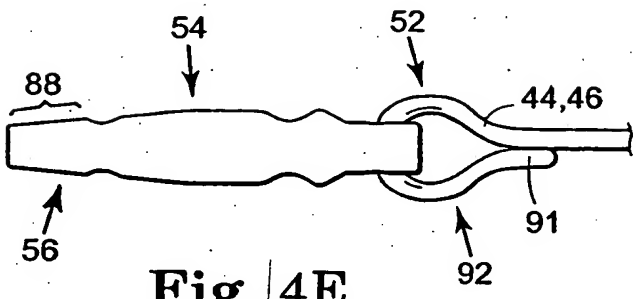


Fig. 4E

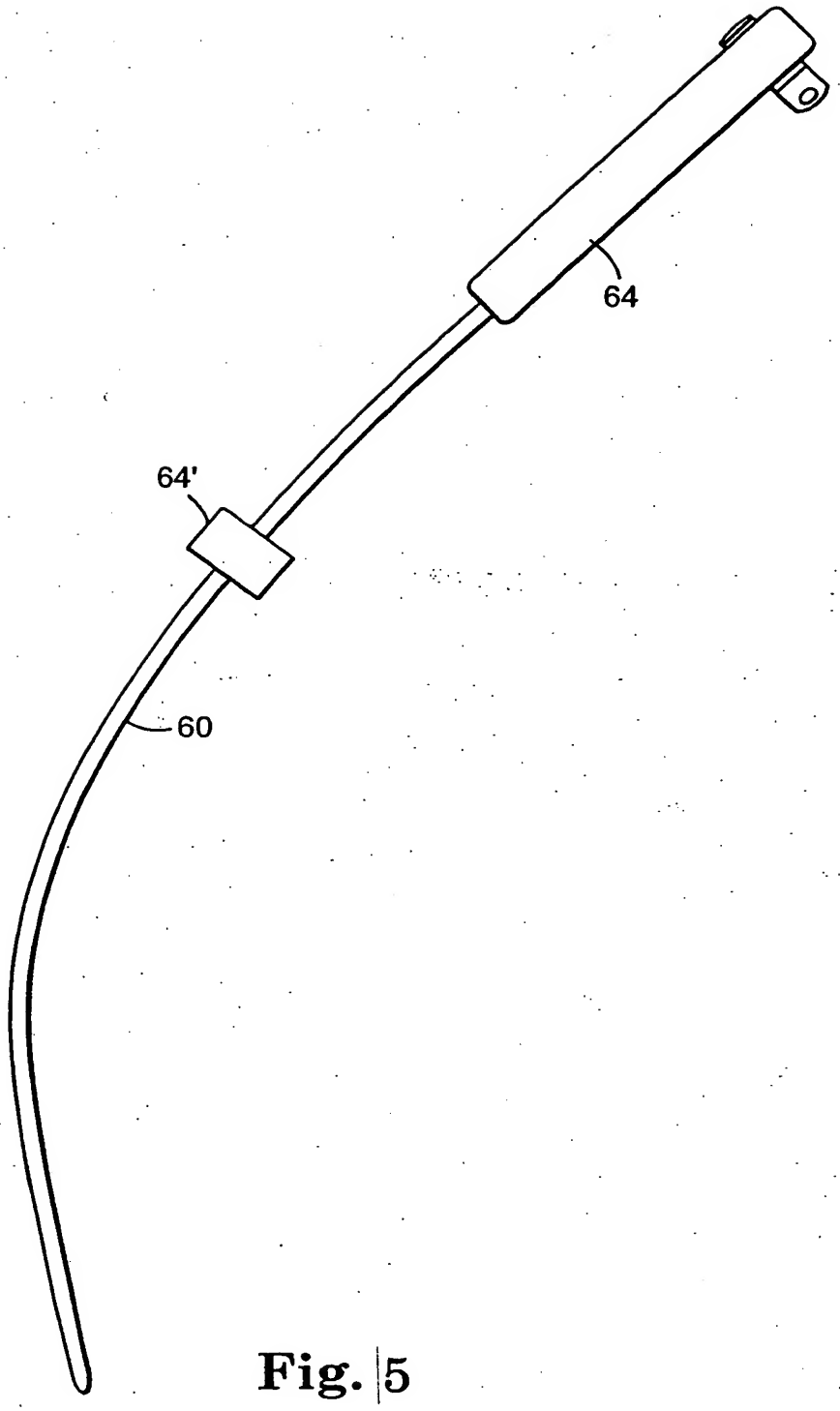


Fig. 5

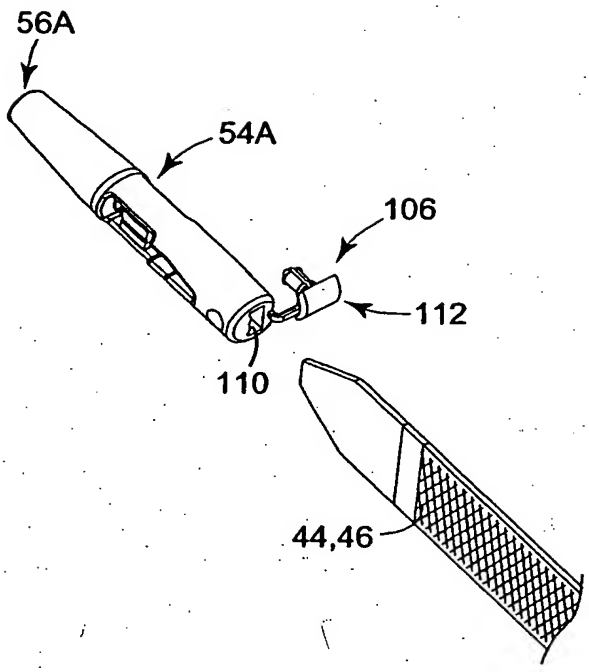


Fig. 6A

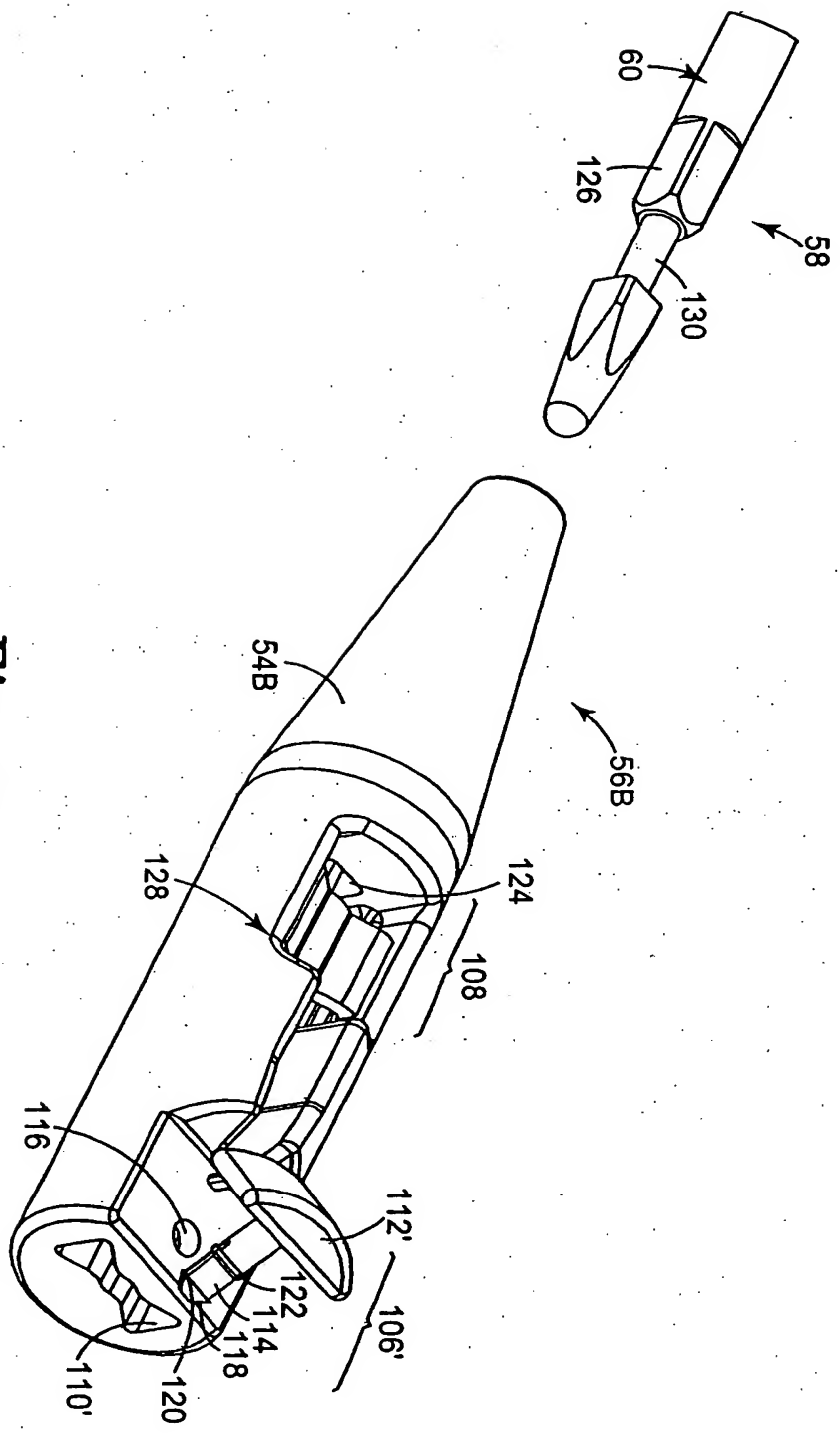


Fig. 6B

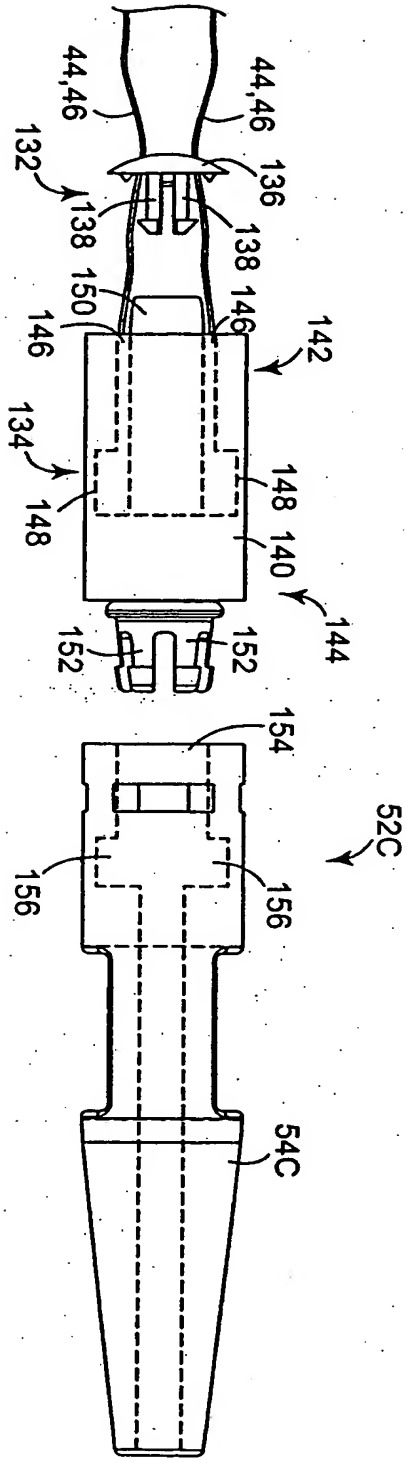
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Fig. 7

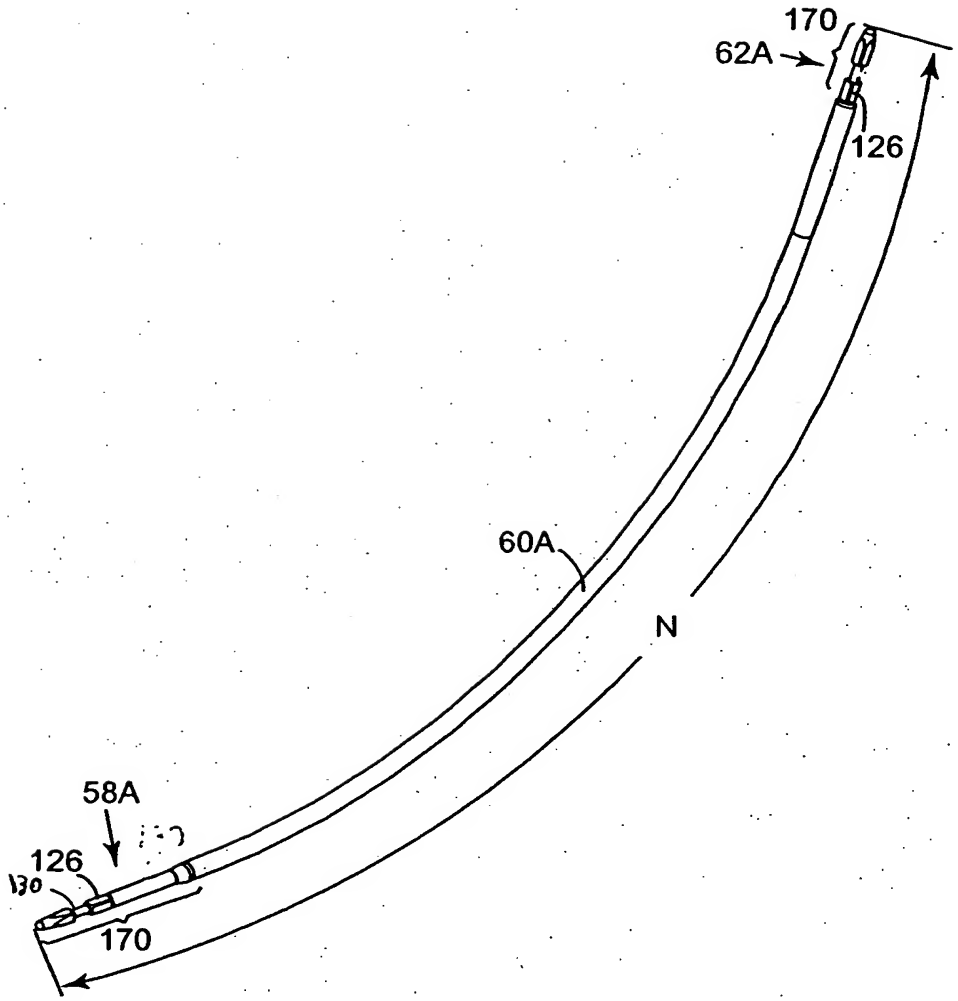


Fig. 8A

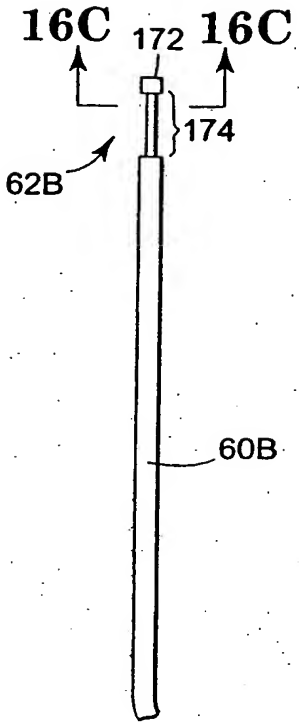


Fig. 8B

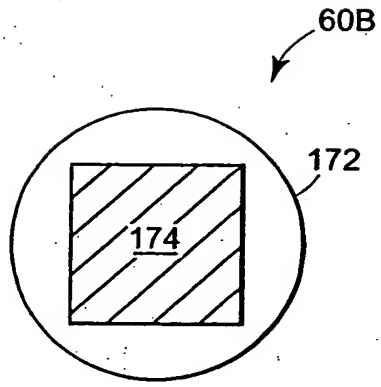


Fig. 8C

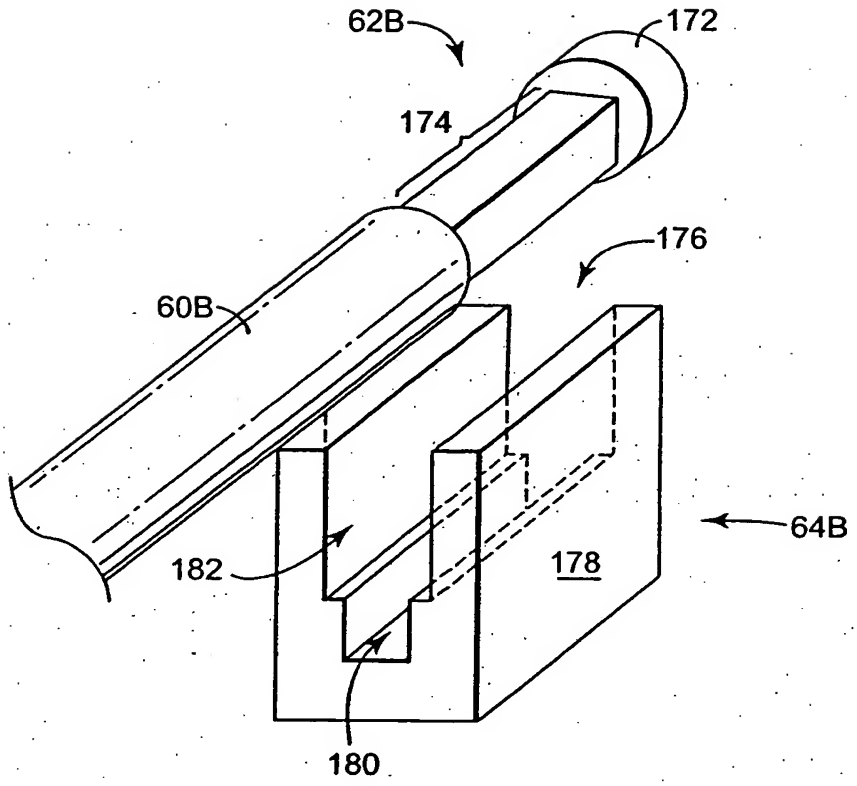


Fig. 8D

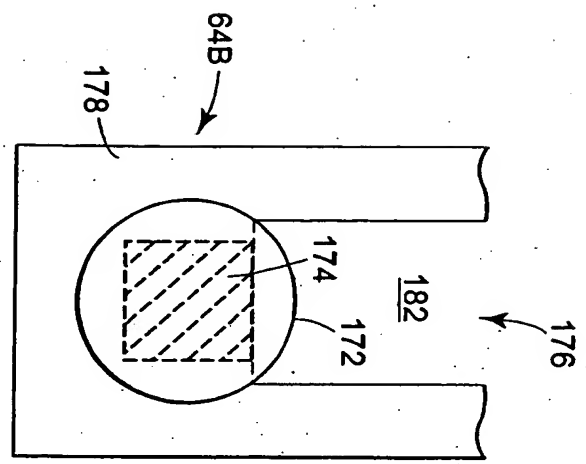


Fig. 8E

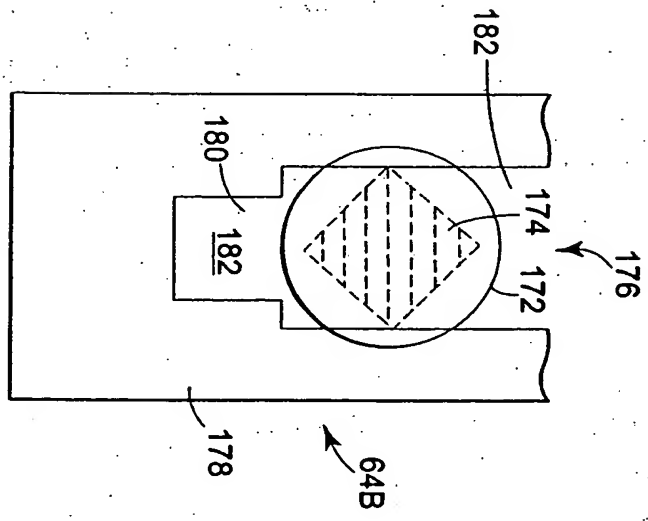


Fig. 8F

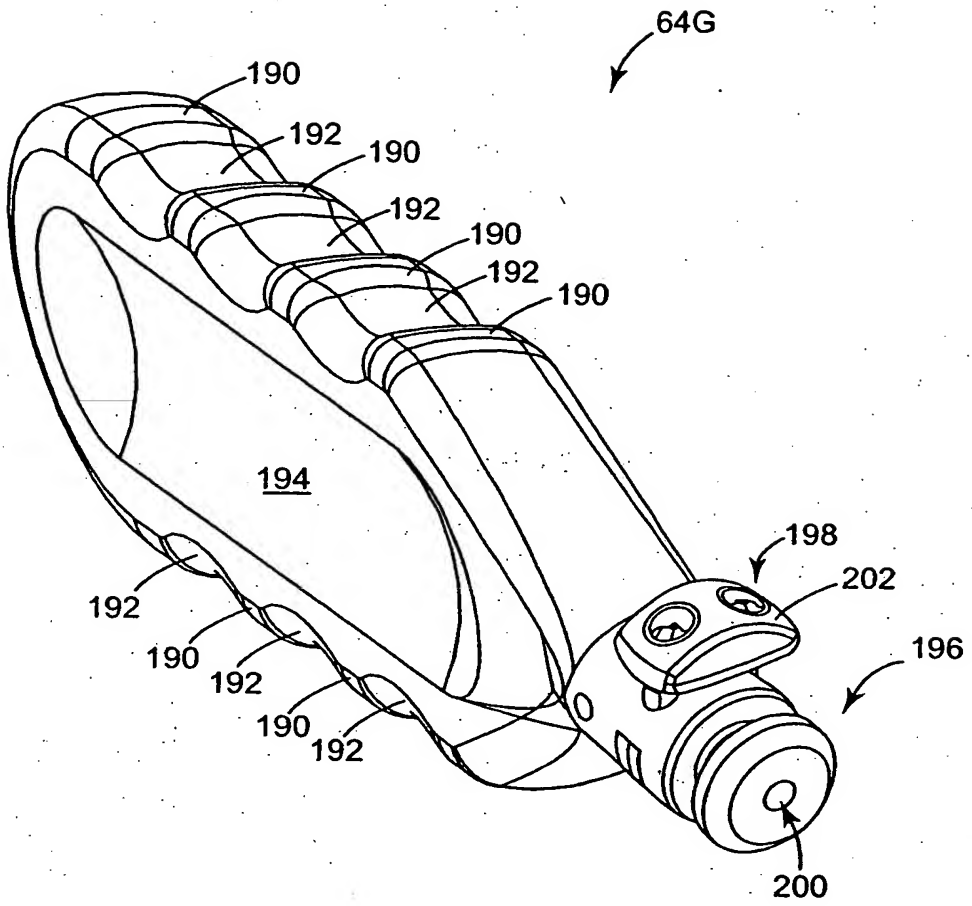
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Fig. 9A

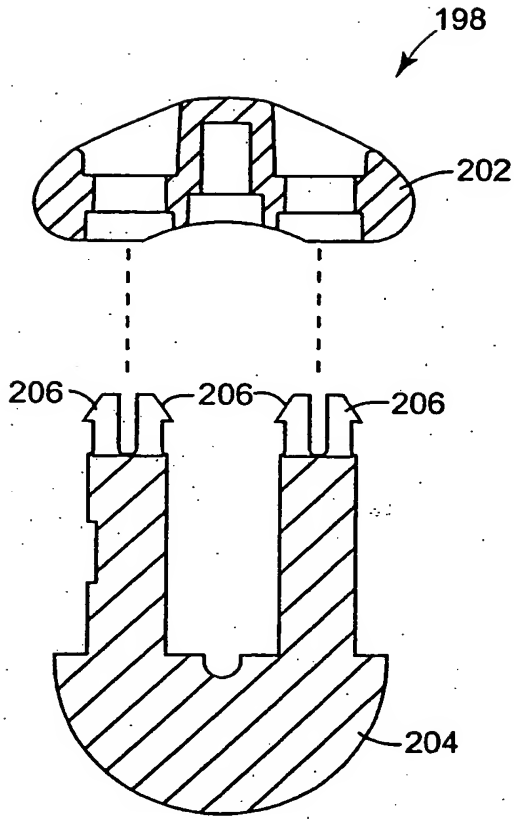


Fig. 9B

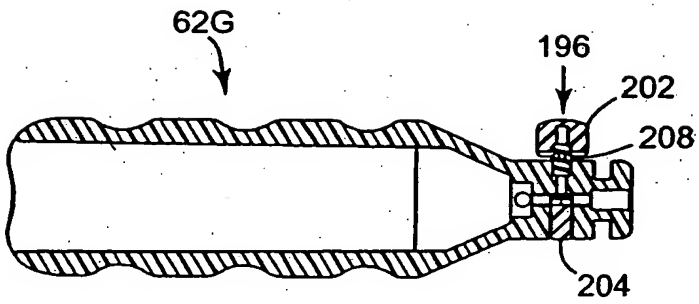


Fig. 9C

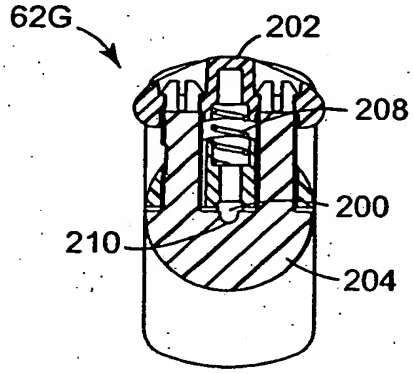


Fig. 9D

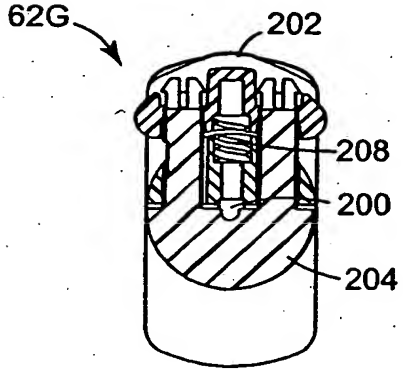


Fig. 9E

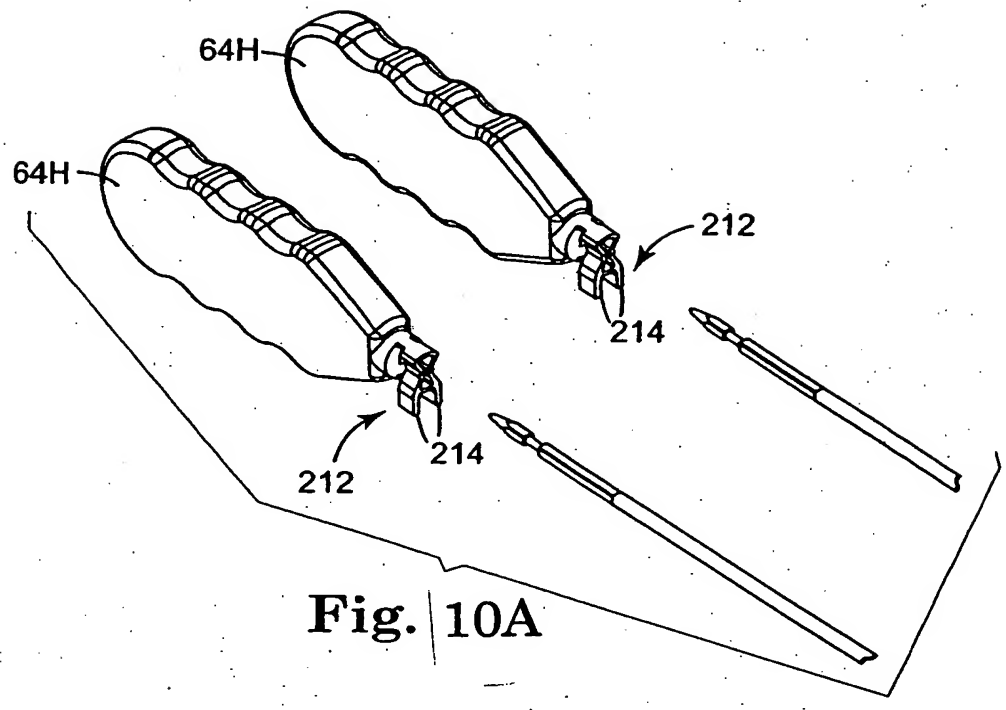


Fig. 10A

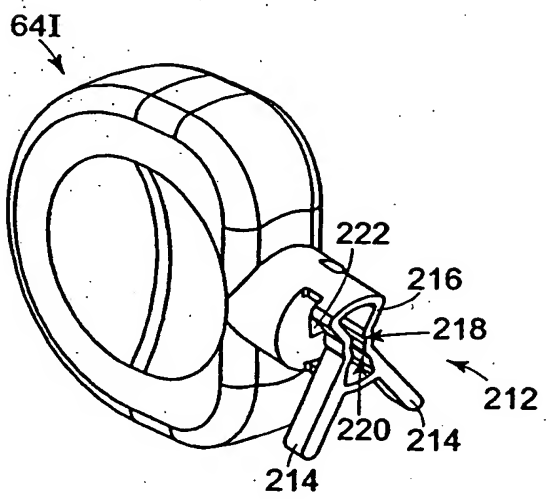


Fig. 10B

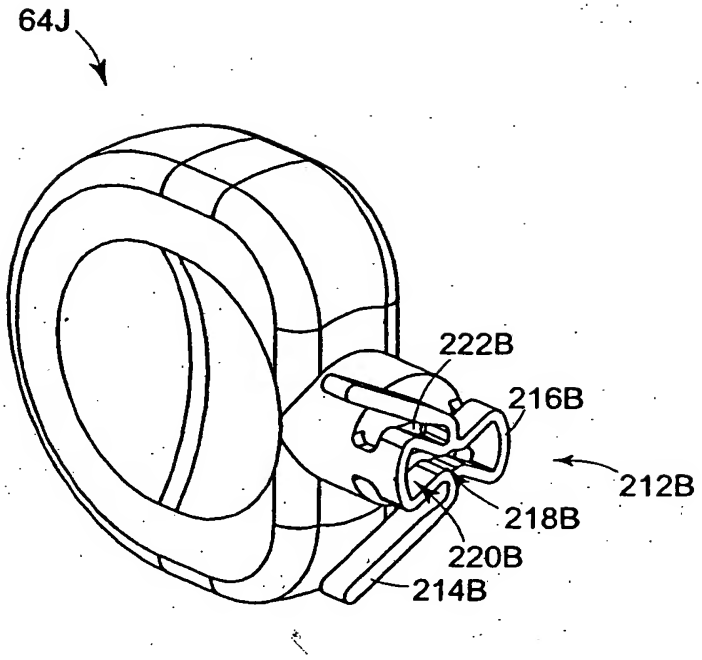


Fig. 10C

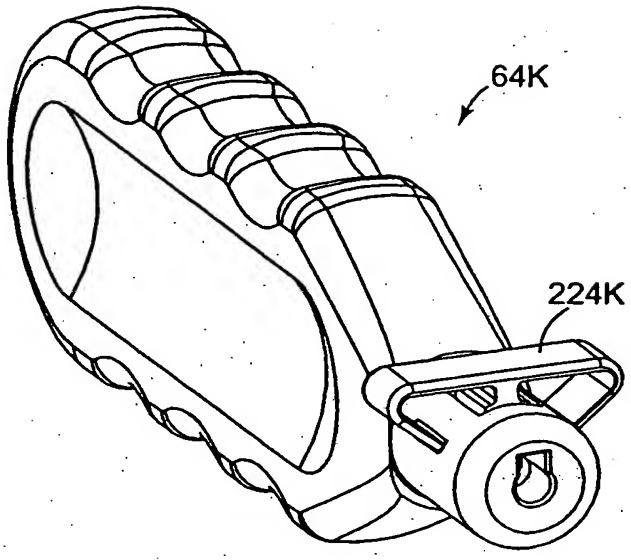


Fig. 11A

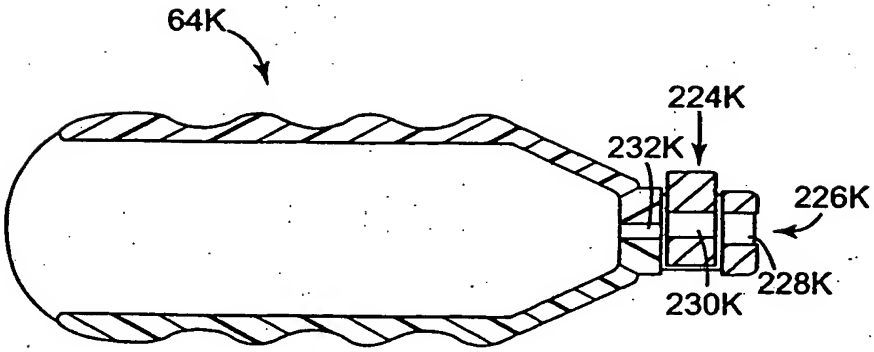


Fig. 11B

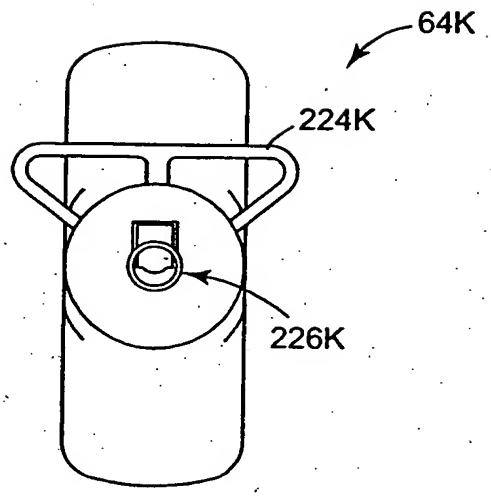


Fig. 11C

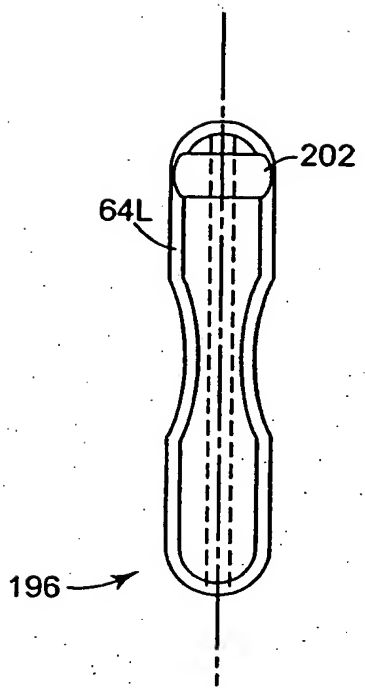


Fig. 12A

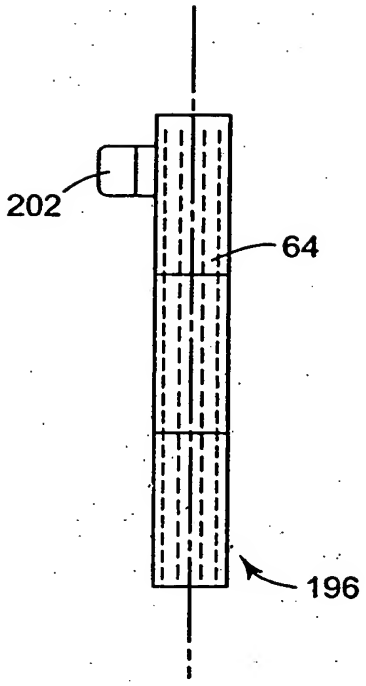


Fig. 12B

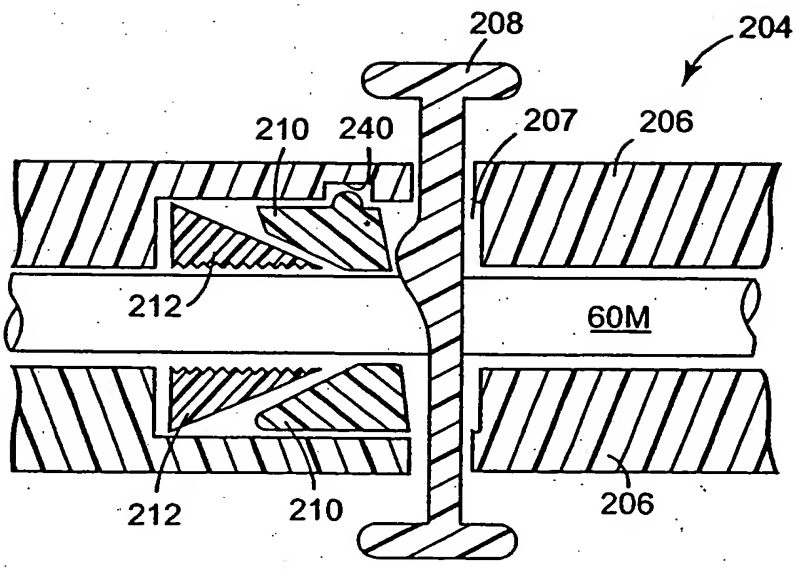


Fig. 13A

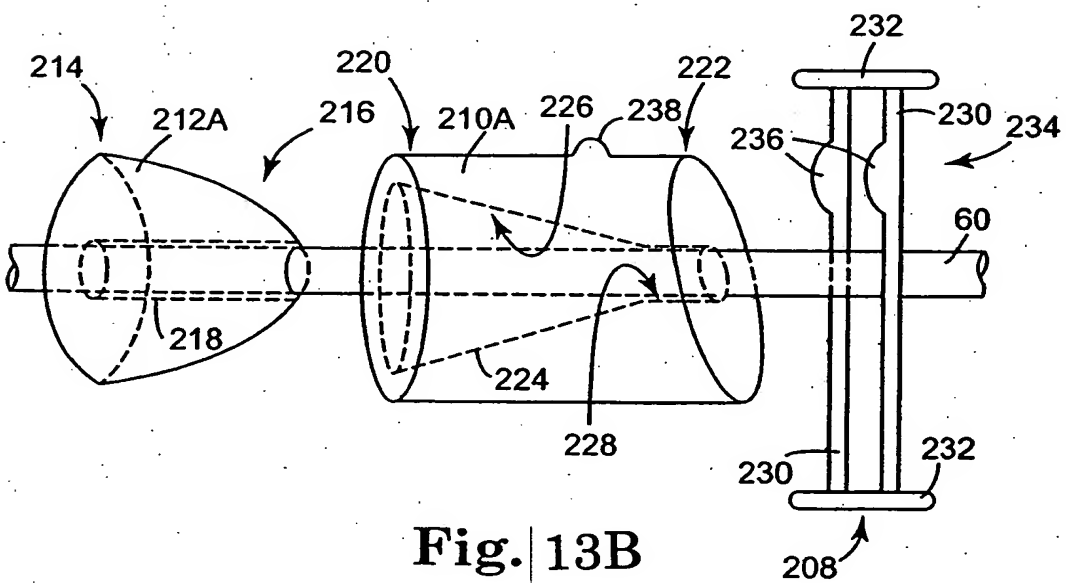


Fig. 13B

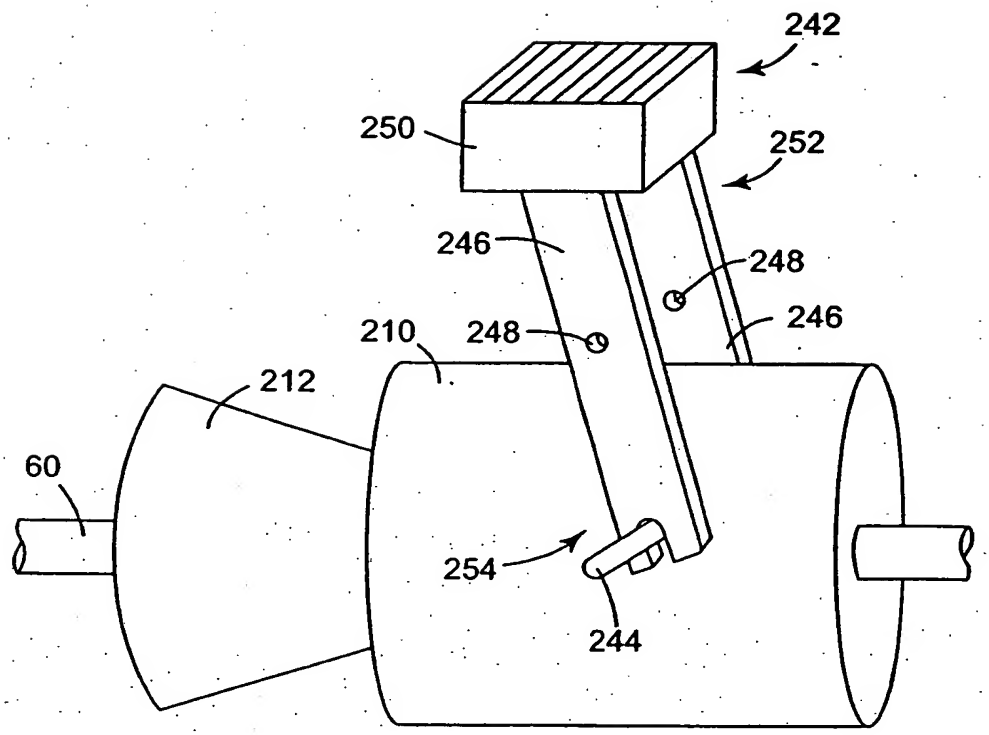


Fig. 14A

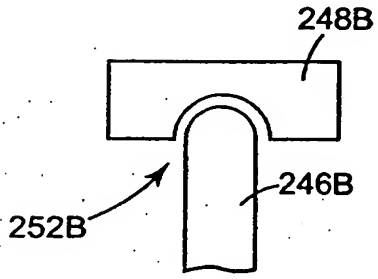


Fig. 14B

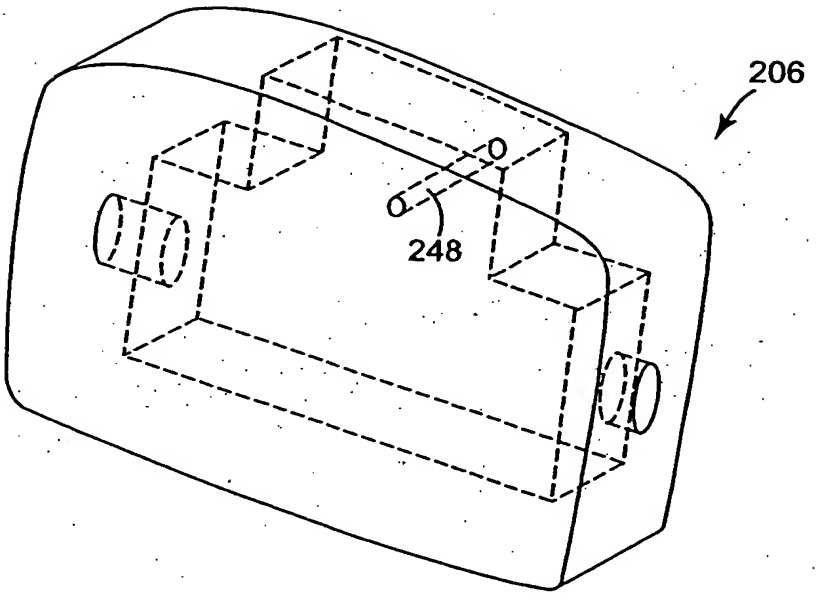


Fig. 14C

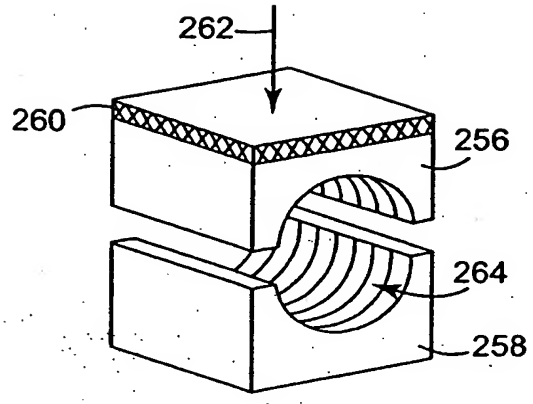


Fig. 15A

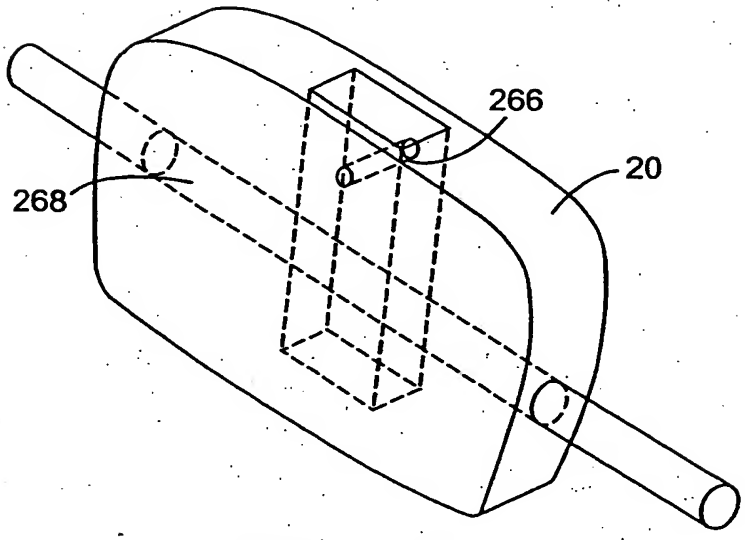


Fig. 15B

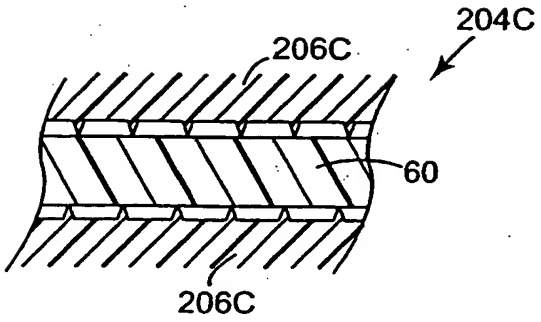


Fig. 15C

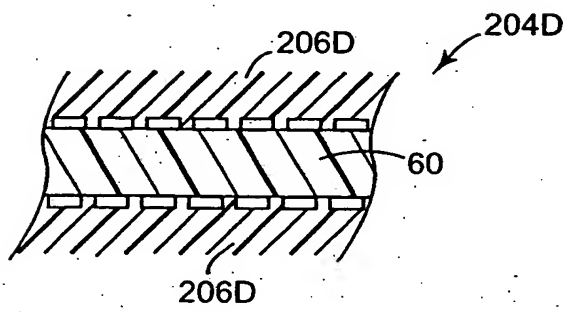


Fig. 15D

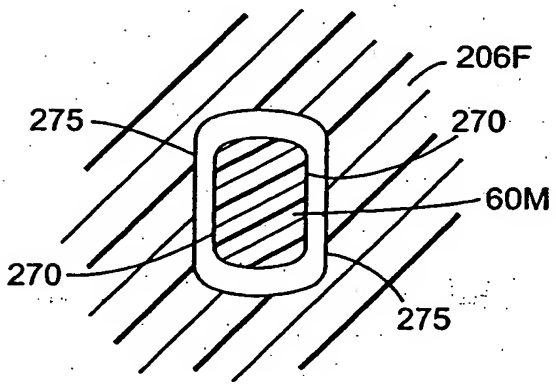


Fig. 15E

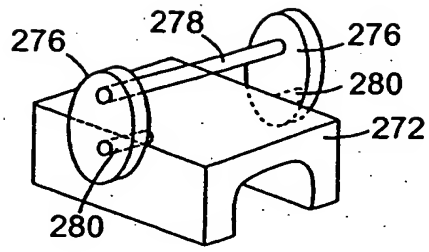


Fig. 16

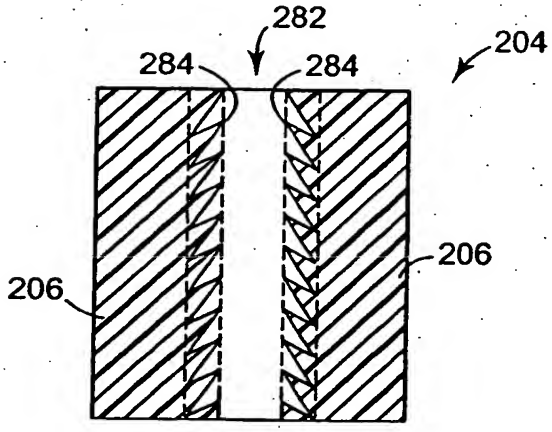


Fig. 17

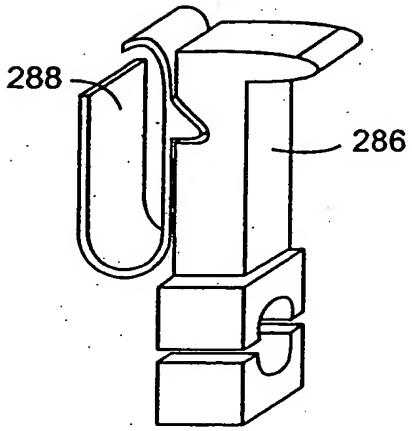


Fig. 18

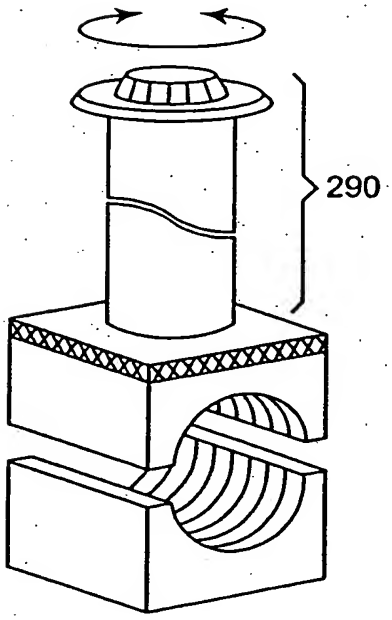


Fig. 19

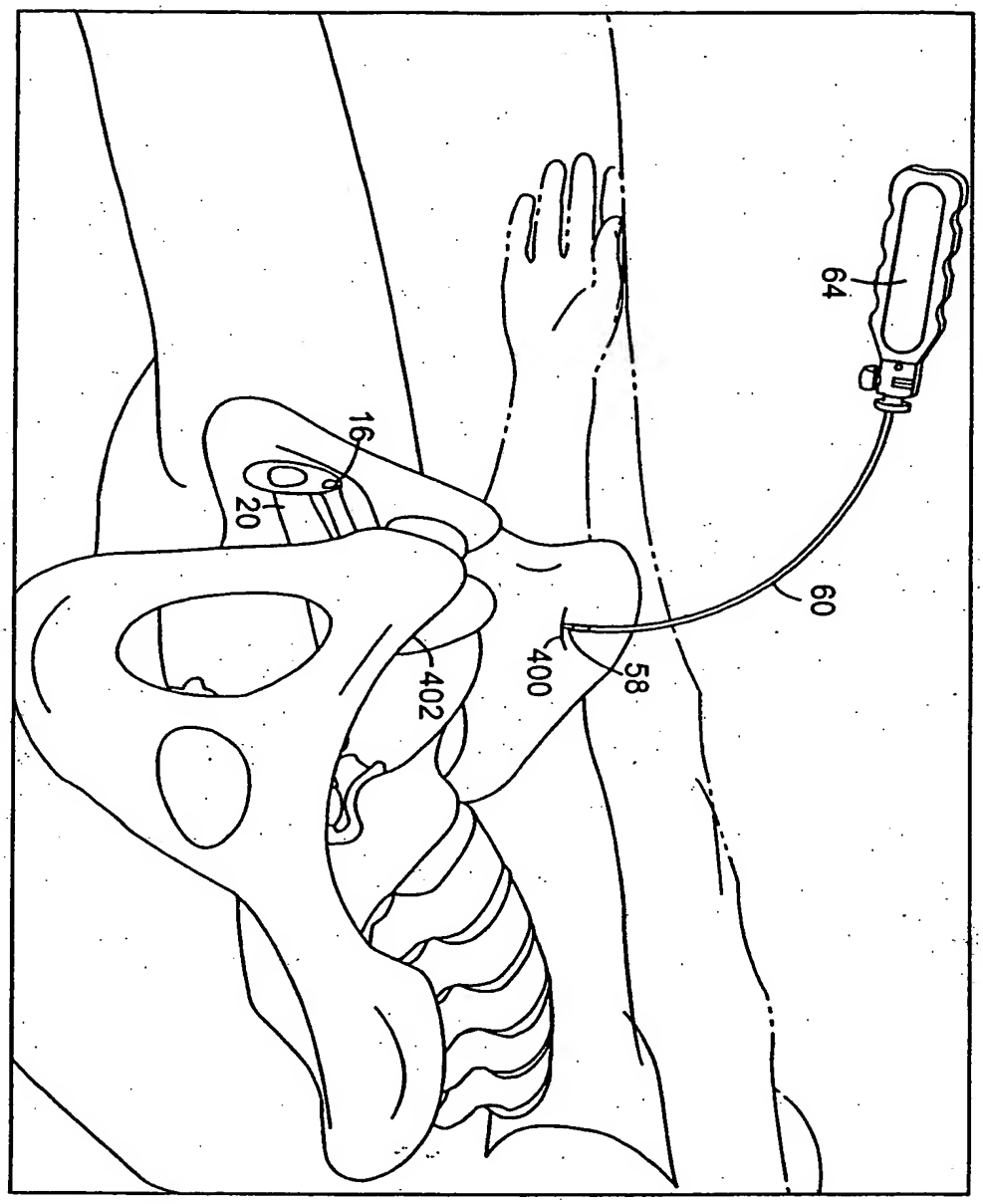


Fig. 20A

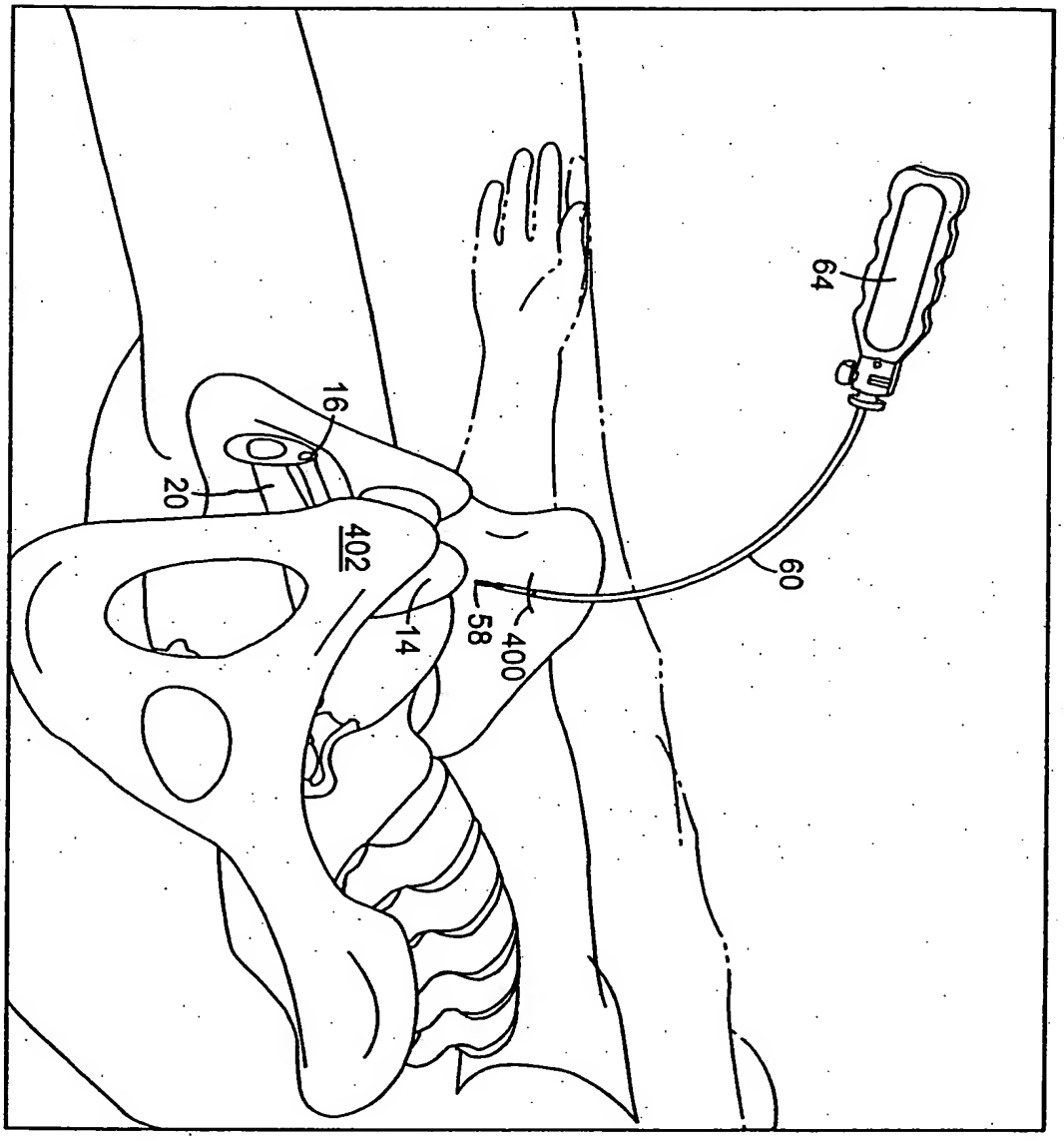


Fig. 20B

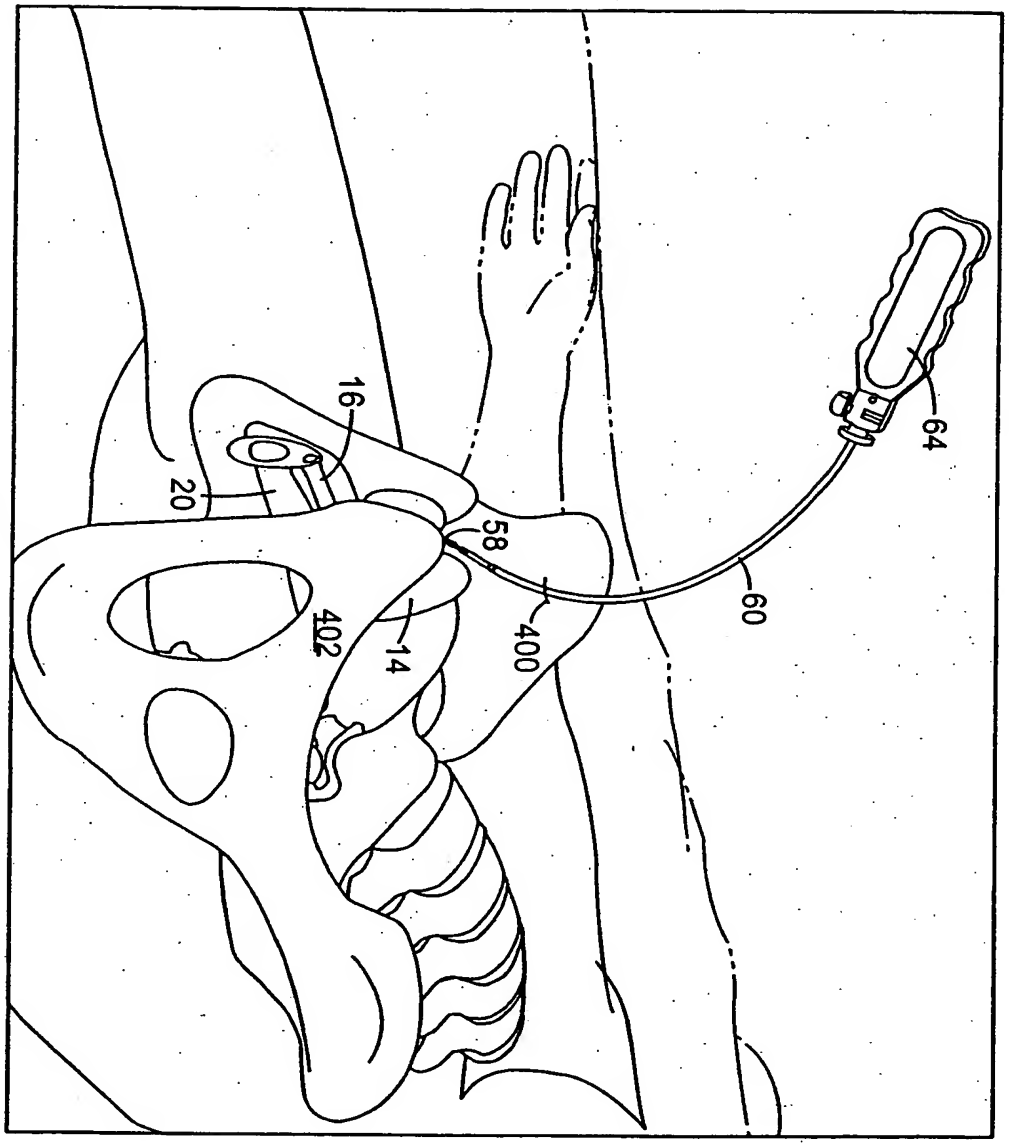


Fig. 20C

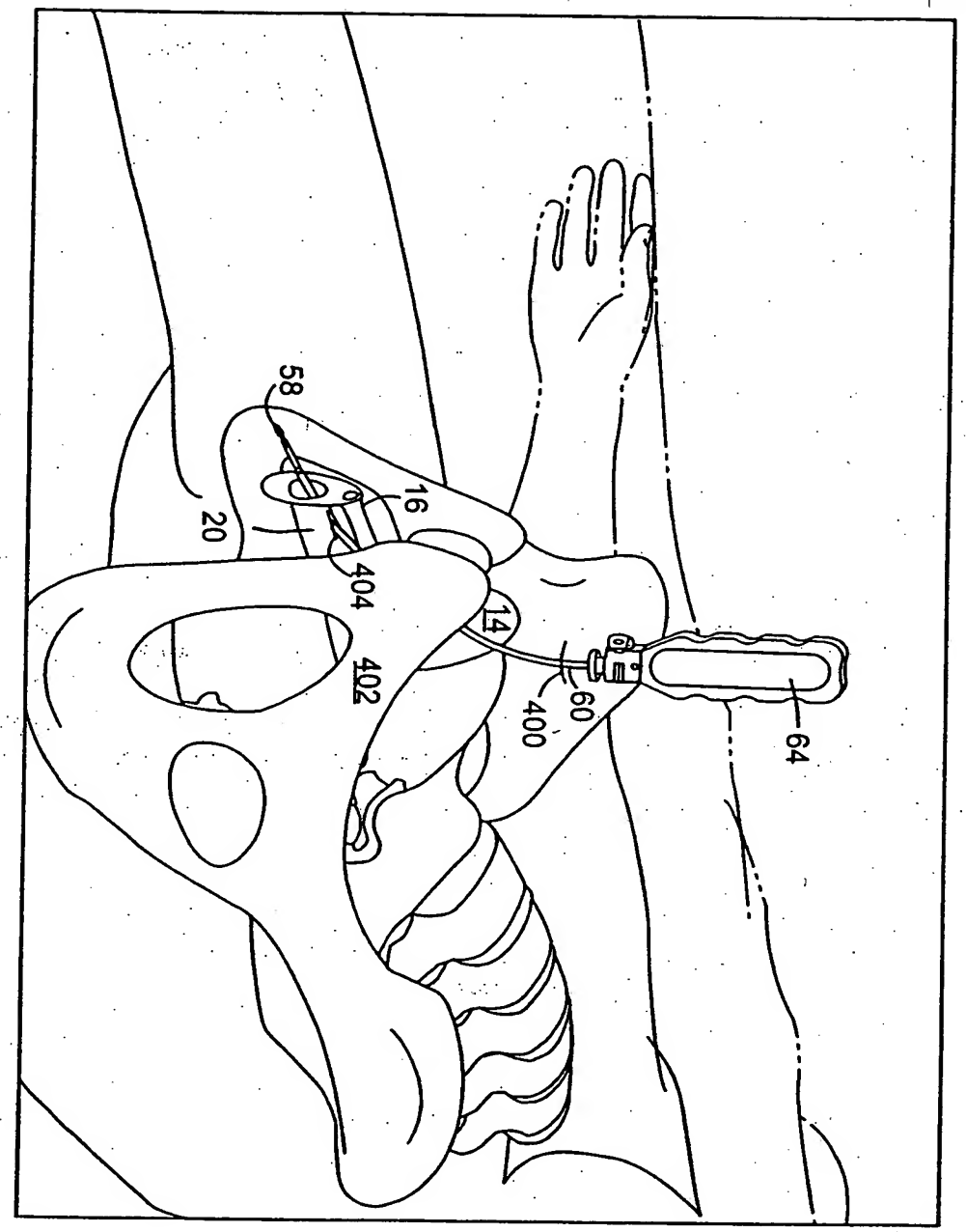


Fig. 20D

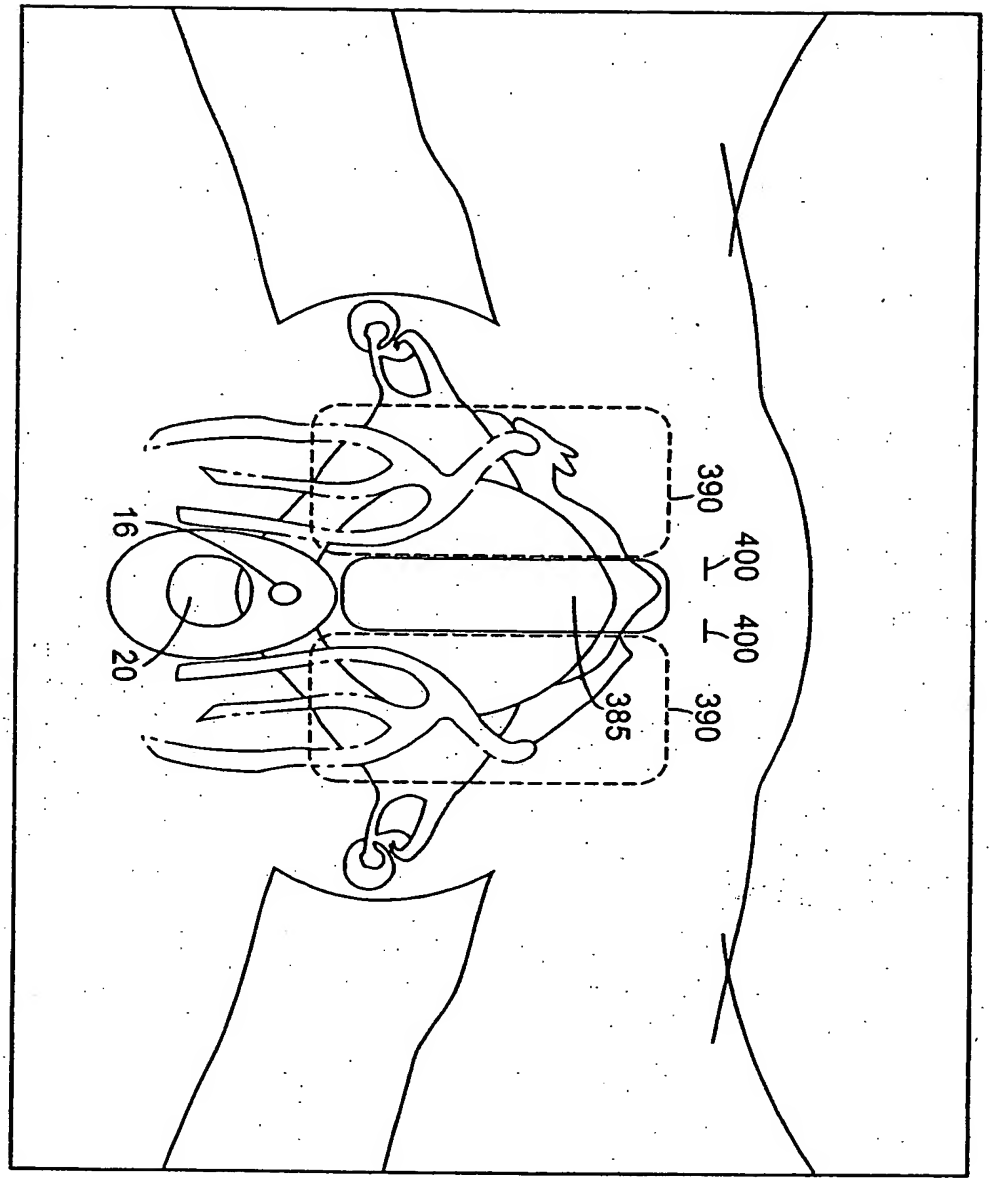


Fig. 21A

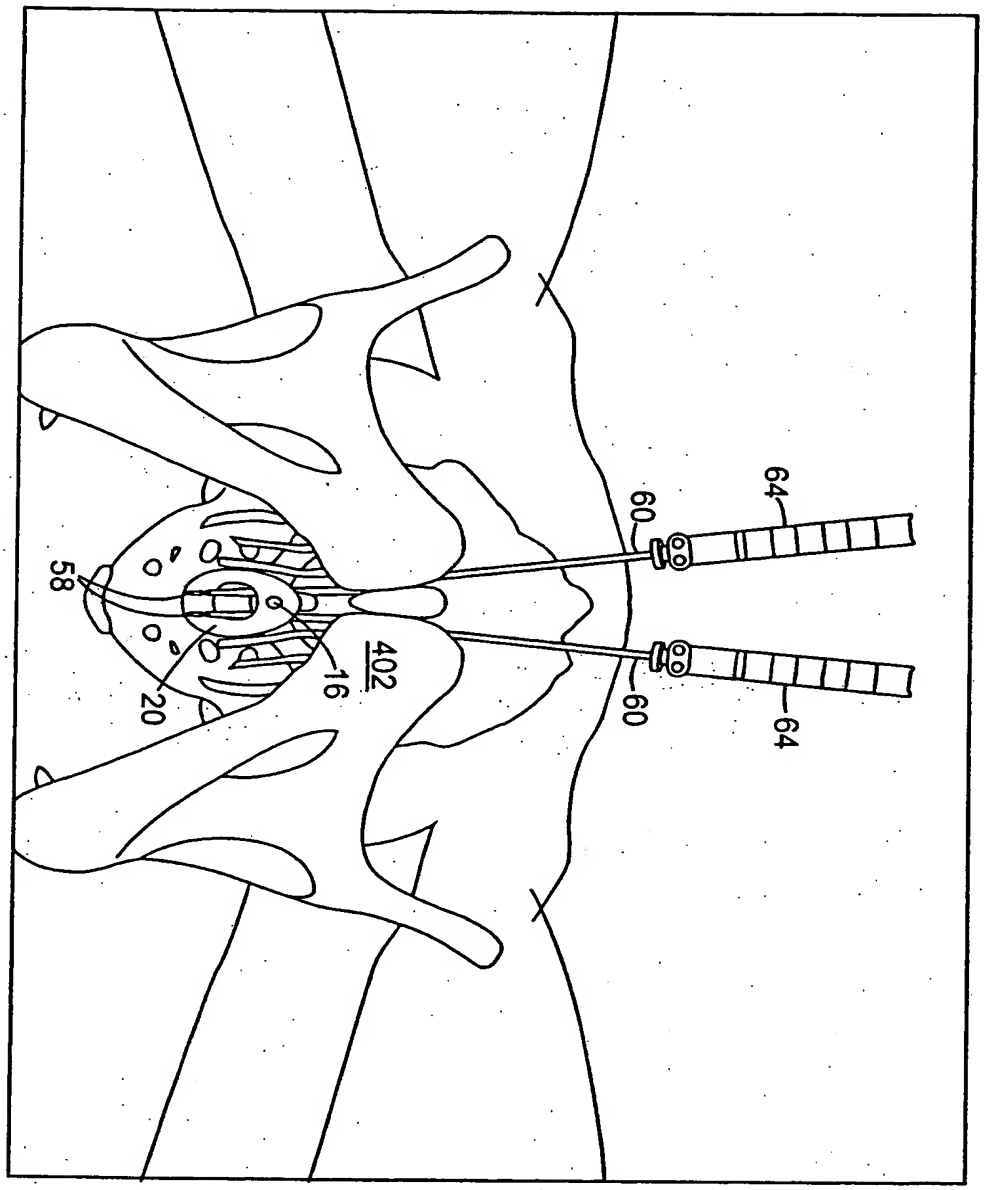


Fig. 21B

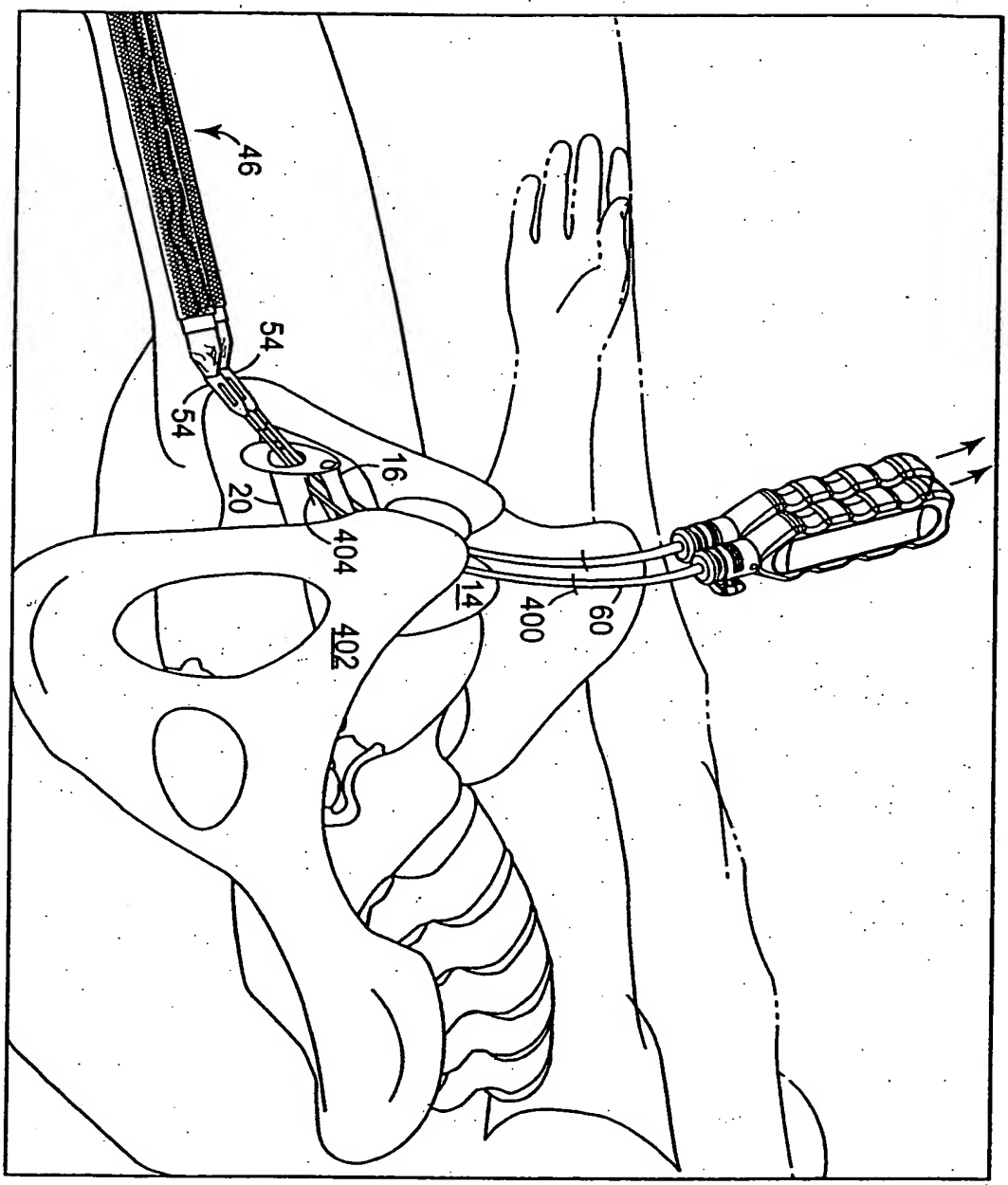


Fig. 21C

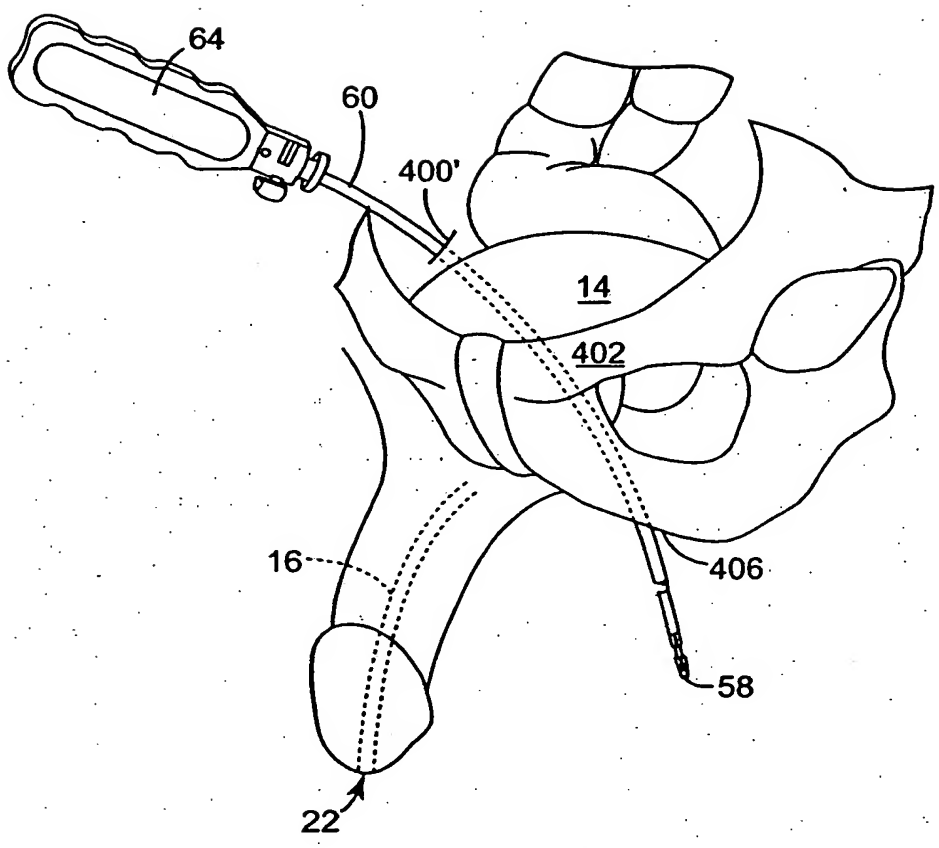


Fig. 22

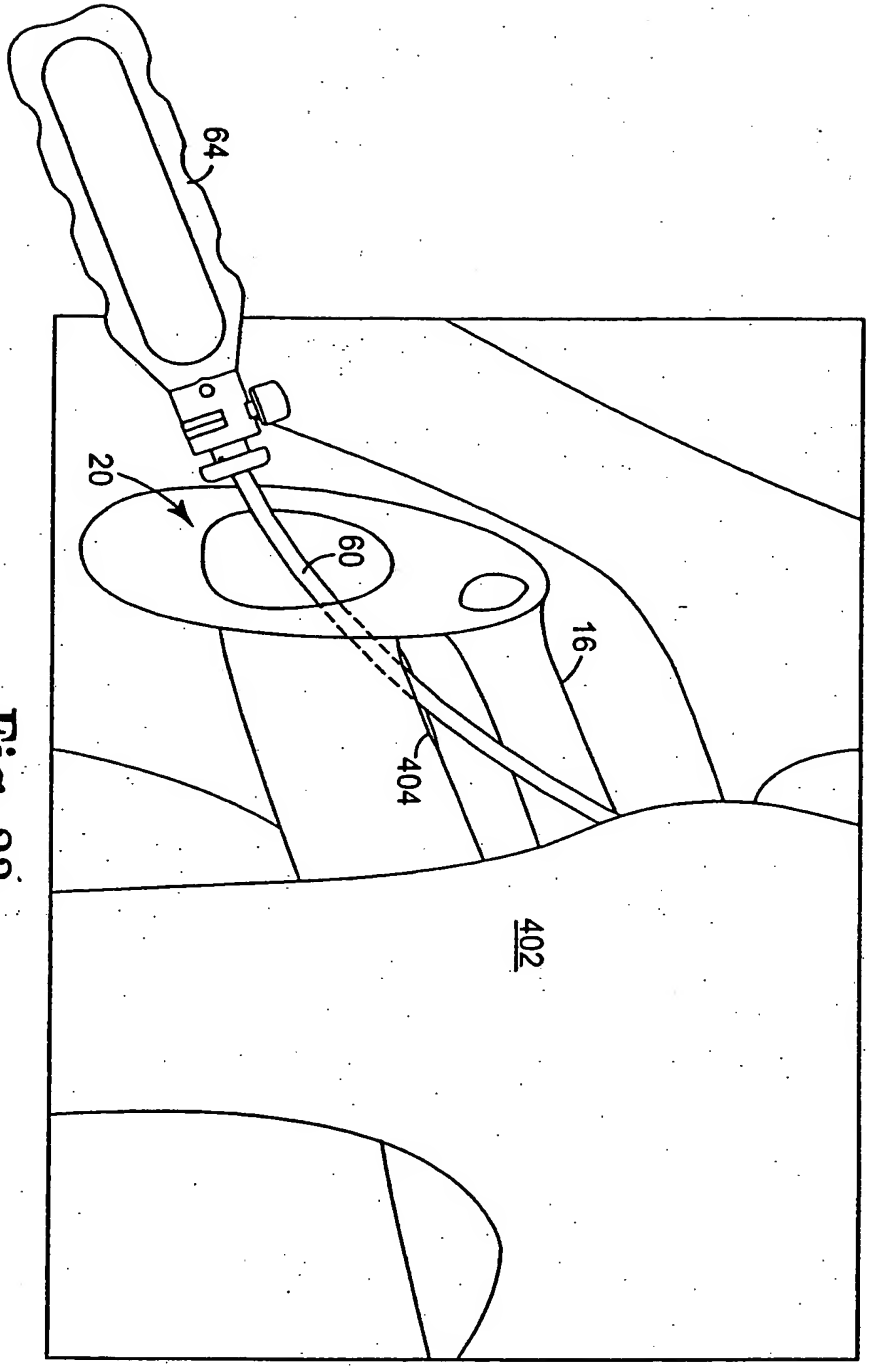


Fig. 23

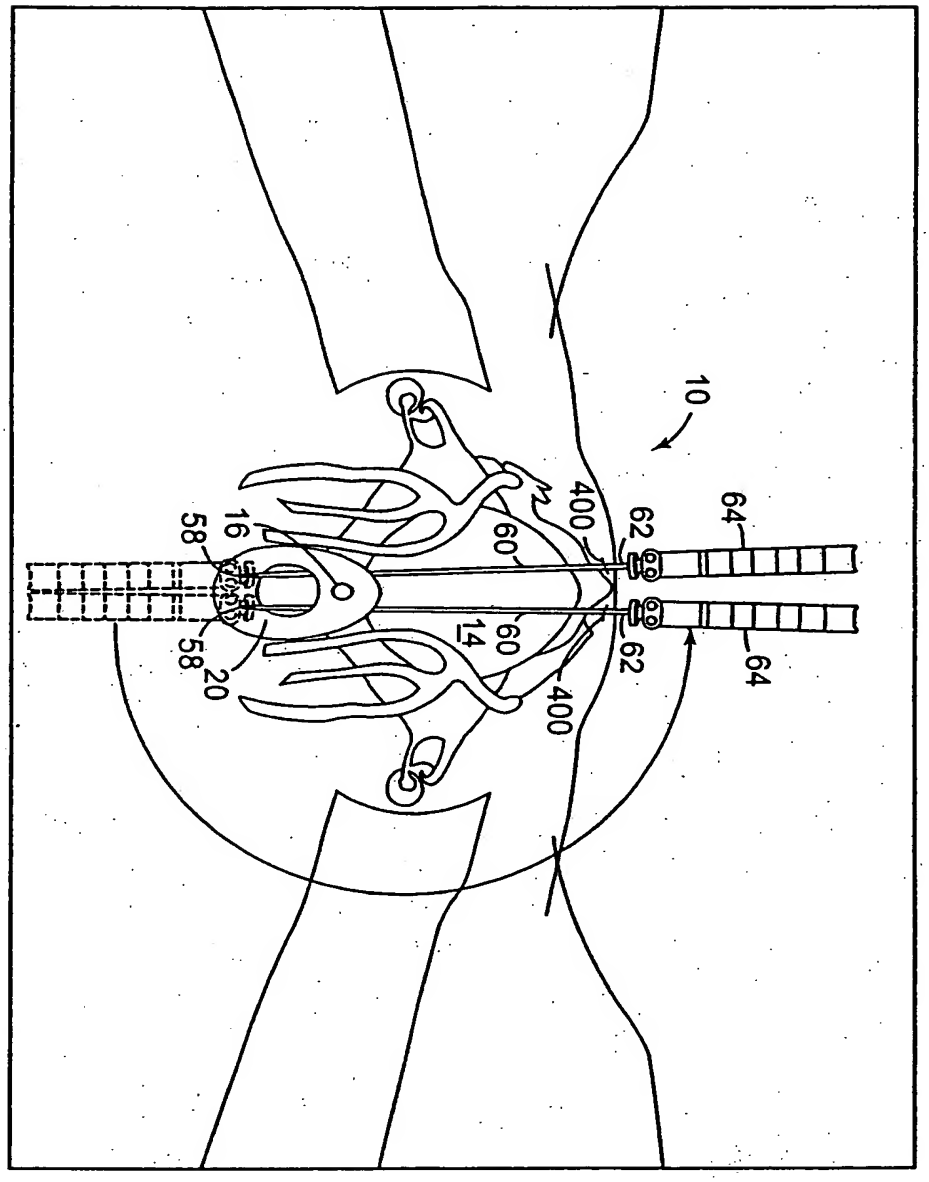


Fig. 24

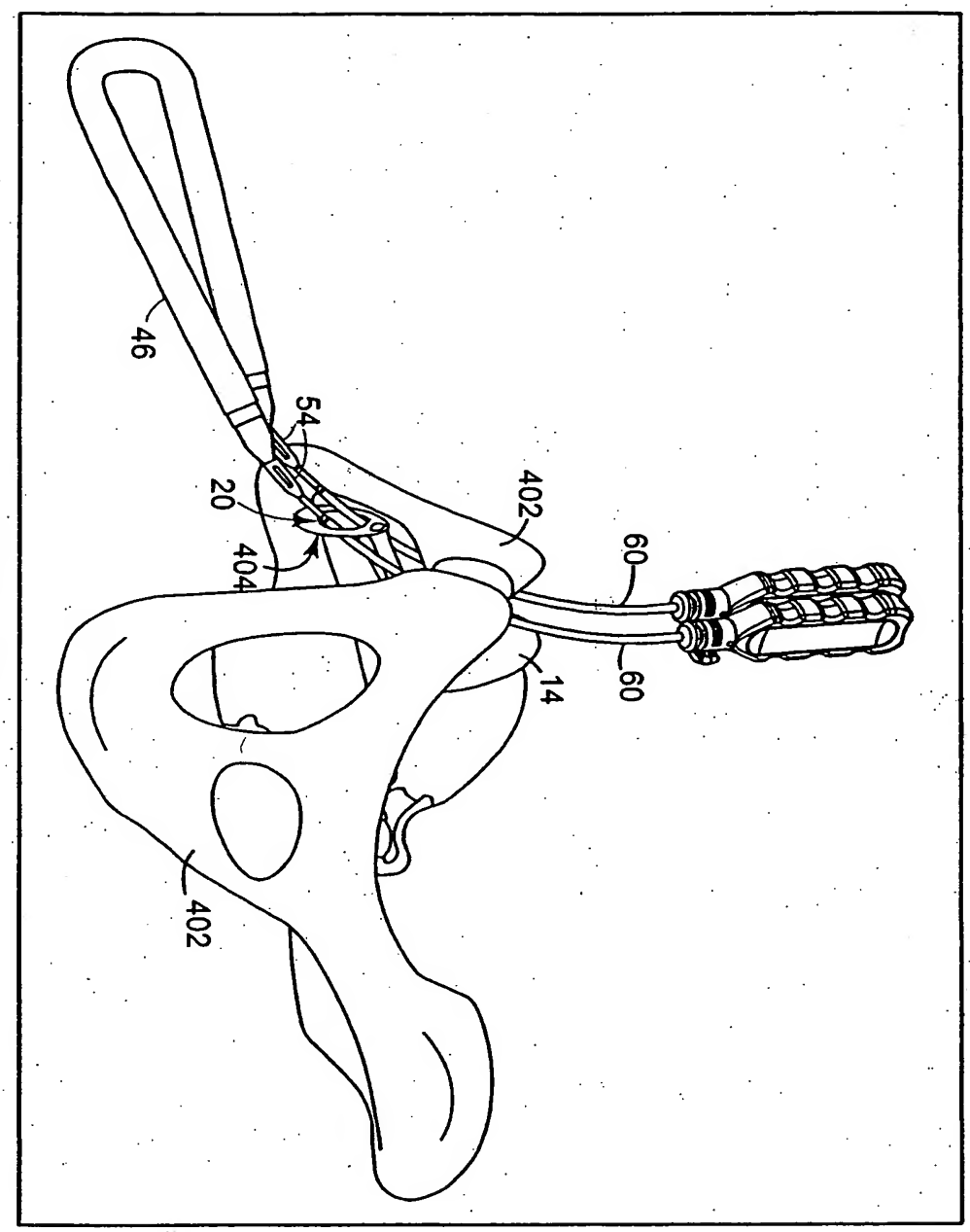


Fig. 25

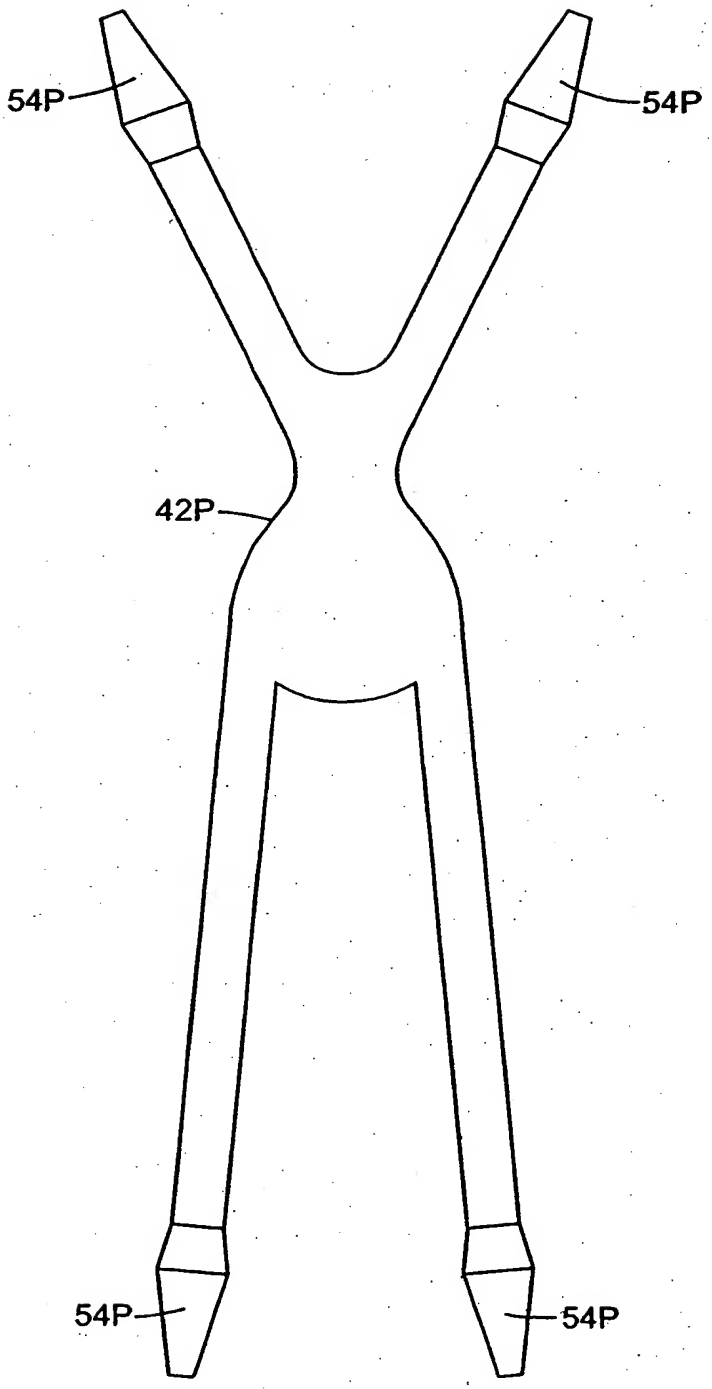


Fig. 26